UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

M.A.C., by his mother Karen Caltieri, Individually and on behalf of all others similarly situated, Plaintiff	:	
v.	:	CIVIL ACTION NO: 1:09-CV-11480-DPW
PFIZER INC., PHARMACIA & UPJOHN CO., Defendants	:	

CIVIL CONSUMER CLASS ACTION AMENDED COMPLAINT

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CIVIL CONSUMER CLASS ACTION COMPLAINT

Plaintiff, M.A.C., a minor, by and through his mother Karen Caltieri, individually, and on behalf of all others similarly situated, by and through his undersigned counsel, brings this Complaint against Defendants Pfizer Inc. ("Pfizer") and its subsidiary Pharmacia & Upjohn Inc. ("Pharmacia") and incorporates by reference thereto the allegations in the cases of *United States et al. ex rel. Stefan Kruszewski v. Pfizer, Inc.,* Civ. No. 07-4106 (E.D.Pa); *United States et al. ex rel. Blair Collins v. Pfizer, Inc.,* Civ. No. 04-11780 (D. Mass.); *United States et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 (D.Mass.); *United States et al. ex rel. David Farber and Casey Schildhauer v. Pfizer, Inc.,* Civ. No. 07-10304 (D. Mass.); *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.,* Civ. No. 07-11728 (D. Mass.); *United States et al. ex rel. Mark Westlock v. Pfizer, Inc., et al,* Civ. No. 08-11318 (D.Mass.); *United States et al. ex rel. Robert A. Liter v. Pfizer, Inc.,* Civ. No. 06-00176 (E.D. Ky.) as set forth in the governing False Claims Act Complaint. (attached hereto as Exhibits 1-7), and further allege as follows:

I. NATURE OF THE CASE

1. This consumer class action is brought by M.A.C., by his mother Karen Caltieri (hereinafter "Plaintiff"), individually and on behalf of a putative nationwide class of similarly situated individuals (the "Class") located throughout Massachusetts and the country for declaratory and injunctive relief and to recover drug payments made from at least January 1, 2001 through at least October 31, 2008 (hereinafter, "the relevant time period") as a result of Defendants' unlawful marketing scheme and conspiracy involving the illegal marketing, promotion and sale of the following prescription drugs: Geodon® ("Geodon"), Zyvox® ("Zyvox"), Lyrica® ("Lyrica"), Aricept®, ("Aricept"), Lipitor® ("Lipitor"), Norvasc®, ("Norvasc"), Relpax® ("Relpax"), Depo-Provera® ("Depo-Provera"), Viagra®, ("Viagra"),

Zithromax® ("Zithromax"), Zoloft® ("Zoloft"), and Zyrtec®, ("Zytec") (collectively referred to as the "Subject Drugs").

2. As described more fully in the False Claims Act Complaints attached hereto and below, Defendants engaged in the following general types of unfair, deceptive and unlawful acts as part of their marketing, promotion and sales scheme and conspiracy: (1) they promoted Subject Drugs to physicians by offering, providing and/or paying various types of improper bribes, kickbacks and other illegal remuneration and inducements, whether or not such Subject Drugs were promoted, prescribed and used for indicated/approved medical conditions and in doses and/or for durations that were indicated/approved; (2) they promoted certain Subject Drugs at doses and/or for durations of use that were not medically safe, efficacious, effective or useful, whether or not such Subject Drugs were promoted, prescribed and used for an indicated/approved medical condition; (3) they made false statements and representations about the safety and efficacy of the Subject Drugs; (4) they promoted Subject Drugs for non-indicated/unapproved or "off-label" uses.

3. Among other things, this Complaint details numerous kickbacks and other types of illegal remuneration and illegal inducements provided by the Defendants to physicians and other healthcare providers to induce them to prescribe the Subject Drugs. For example, the Defendants provided remuneration as inducements to physicians and other healthcare providers to treat patients with certain Subject Drugs. Defendants' illegal course of remuneration and inducements to physicians destroyed the independence of the physician in treating patients like the Plaintiff and others similarly situated.

4. Pfizer sales representatives pushed doctors to prescribe Geodon for treatment of various unapproved conditions such as anxiety, depression, autism, and attention-

deficit/hyperactivity disorder and for treatment in children. The FDA had approved Geodon only to treat schizophrenia and bipolar disorder in adults. Pfizer targeted child psychiatrists, family doctors and pediatricians to expand off-label use and maintained on its payroll an army of more than 250 child psychiatrists nationwide.

5. The illegal marketing, promotion and sales scheme and conspiracy, in its various forms, as described herein, caused the Plaintiff, M.A.C., and members of the Class to pay hundreds of millions, if not billions, of dollars for the Subject Drugs. As discussed herein, Pfizer's subsidiary, Pharmacia & Upjohn, has been investigated by and settled with several governmental agencies regarding this fraudulent and wrongful conduct and admitted, pled guilty to and was convicted as to certain core aspects of the fraudulent marketing, promotion and sales scheme and conspiracy with respect to Bextra, a drug not at issue in this case. As discussed below, on September 2, 2009, the U.S. Department of Justice (the "DOJ") announced a $2.3 billion settlement arising from Pfizer's fraudulent and criminal promotion of at least 13 different regulated drugs. The DOJ described the underlying misconduct as so pervasive and embedded in Pfizer's corporate culture that it required "the largest criminal fine ever imposed in the United States for any matter" and the "largest civil fraud settlement in history against a pharmaceutical company." In announcing the settlement, the U.S. Attorney for the District of Massachusetts attributed the severity of the fines to "Pfizer's recidivism," lamenting that "at the very same time Pfizer was in our office negotiating and resolving [prior] allegations of criminal conduct… Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

6. Pfizer's historic $2.3 billion settlement follows numerous prior regulatory and enforcement actions well known to the Board and senior executives. This was at least Pfizer's

fourth major fine, and third criminal guilty plea, for illegal marketing and sales practices since 2002. Indeed, settlements in 2002, 2004, and 2007 had already cost Pfizer a combined $513 million in fines. Moreover, as a result of these earlier instances of misconduct, Defendants had specifically agreed—pursuant to "Corporate Integrity Agreements" reached with regulators—to establish and administer internal compliance mechanisms to directly inform the Board of the Company's compliance or non-compliance with the drug marketing laws. Nevertheless, despite repeated legal violations within the Company and the overwhelming "red flags" confronting the Board, the directors continued to look the other way.

7. In 2002, Pfizer and its wholly-owned subsidiary, the Warner Lambert Company ("Warner Lambert"), agreed to pay $49 million to settle allegations concerning the payment of illegal kickbacks to health professionals for prescribing Pfizer's anti-cholesterol drug "Lipitor." Regulators placed the responsibility for rectifying the Company's prior practices squarely on Pfizer's Board and senior executives, insisting that Pfizer enter into the earliest "Corporate Integrity Agreement," whereby the Board was required to receive directly "periodic (at least semi-annual" reports regarding compliance matters" from a specifically designated Compliance Officer, and which provided that the Compliance Officer was also "authorized to report on such matters to the Board of Directors at any time." Notwithstanding the 2002 Corporate Integrity Agreement, and the specific responsibilities assumed by the Board in this agreement, Pfizer's use of illegal kickbacks and other systematic violations of the drug marketing laws continued unabated.

8. In 2004, another Pfizer subsidiary pled guilty to criminal charges for misbranding Pfizer drug "Neurontin," including the illegal and deceptive promotion of off-label uses and doses. This time, the government ratcheted up its demands, settling only when Pfizer agreed to

pay a $240 million criminal fine, which the DOJ noted at the time was "the second largest criminal fine ever imposed in a health care fraud prosecution." Pfizer also paid $190 million that necessarily alerted the Board to the risks presented by the Company's endemic pattern of unlawful marketing practices. Recognizing this fact, regulators once again placed responsibility for addressing the Company's pattern of illegal drug marketing with the Board, which agreed to a second "Corporate Integrity Agreement" aimed at preventing future violations. The 2004 Corporate Integrity Agreement—which imposed even more stringent obligations on the Board than its predecessor—was another empty promise.

9. In 2007, Pfizer again faced criminal sanctions for illegal marketing. Pfizer subsidiary Pharmacia entered a criminal guilty plea for the illegal promotion and sales practices of Pfizer drug Genotropin, a human growth hormone (anabolic steroid). To settle the charges, Pfizer entered into a deferred prosecution agreement with the U.S. Attorneys' Office in Massachusetts and agreed to pay yet another $34.6 million in criminal fines.

II. PARTIES

10. This action is brought by Plaintiff, M.A.C., a minor, by his mother Karen Caltieri, individually and on behalf of all other individuals similarly situated.

11. Plaintiff resides at 144 Lindset Street, Attleboro, Massachusetts, 02703, and who, during the relevant time period, was prescribed and paid for Geodon, a Subject Drug in this action, for treatment of Attention-deficit/hyperactivity disorder ("ADHD"). As discussed in more detail below, Geodon is an "atypical" antipsychotic approved by the FDA for the treatment of (1) schizophrenia; (2) acute agitation in schizophrenic patients; and (3) acute bipolar Mania including both manic and mixed episodes. It is not approved for treatment of children or ADHD. Dr. Sharon K. Winters, M.D. of "Winters Family Psychiatry" treated Plaintiff for ADHD from

approximately the year 2003 to 2006. Plaintiff was about six years old when Dr. Winters prescribed Geodon to help him sleep and relax. Neither the Plaintiff nor his mother were informed at any time that Geodon was not FDA approved for treatment of ADHD or for any condition in children. Throughout the course of his treatment, Plaintiff's condition never improved and M.A.C. did not benefit from the treatment at all. He did, however suffer side effects from his treatment with Geodon. At no time during the relevant time period was either Plaintiff or his mother aware of any aspect of any marketing and sales scheme, conspiracy or other illegal conduct averred in this Complaint. Like other members of the Class, Plaintiff suffered damages as a result of the scheme and conspiracy committed by Defendants.

12. Defendant Pfizer, Inc., ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY. Pfizer merged with Pharmacia in 2002 and, since then, has merged with a number of other pharmaceutical companies, including, Pharmacia, Upjohn, Searle, and Sugen. On January 26, 2009, Pfizer agreed to buy Wyeth for $68 billion. Pfizer is the world's largest research-based biomedical and pharmaceutical company and currently ranks number one in pharmaceutical sales in the world with a reported $48.3 billion in revenue in 2008. Pfizer is a global company principally engaged in the research, manufacture and sale of prescription pharmaceuticals throughout the United States, and the world. At all times relevant hereto, Pfizer engaged or assisted in the manufacture, distribution, sale, promotion and/or marketing of numerous prescription pharmaceuticals. Upon information and belief, Pfizer, at all times relevant hereto, also directed, engaged or assisted in the illegal conduct with respect to the Subject Drugs that are the subject of this Complaint.

13. Defendant Pharmacia & Upjohn Co., Inc., ("Pharmacia") is a wholly-owned subsidiary of Pfizer. Pharmacia & Upjohn was created in 1995 by the merger of Upjohn with

Pharmacia AB. Pharmacia & Upjohn was later re-created as Pharmacia on April 3, 2000 when Monsanto's Searle Pharmaceuticals division was merged together, prior to merging with Pfizer in 2002. Upon information and belief, Pharmacia, at all times relevant hereto, assisted in directing, engaged or otherwise assisted in the manufacture, distribution, sale, promotion and/or marketing of Pfizer's prescription pharmaceuticals, and specifically in the illegal conduct with respect to the Subject Drugs that are the subject of this Complaint.

14. The acts alleged in this Complaint to have been done by each of the defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

15. Various persons and/or firms, not directly named as defendants herein, including various medical providers and insurers located throughout the country, have participated as co-conspirators in the violations alleged herein and have performed acts and made statements or omissions in furtherance thereof.

III. JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. §§ 1332(a) and 1332(d), because the matter in controversy exceeds $5 million exclusive of interest and costs, and because more than two-thirds of the members of the putative Class are citizens of states different from that of the Defendants.

17. A substantial part of the events or omissions giving rise to the claims in this action occurred in this judicial District and Defendants may be found within this judicial District. Venue is proper in this jurisdiction under 28 U.S.C. § 1391. In fact, Ronald Rainero and Mark

R. Westlock, who have personal knowledge of the allegations herein, filed Qui Tam Cases against Pfizer on behalf of the federal government in this District.

18. Defendants implemented their fraudulent marketing scheme in this District, as well as nationwide, through healthcare providers, sales and other representatives, agents, and others who reside and/or transact business in this District. Defendants' scheme, as alleged herein, thereby affected Class members who reside or transact business throughout the United States, including within this District. Accordingly, Defendants have submitted themselves to the jurisdiction of this Court by committing tortious acts within this State and this judicial District specifically.

IV. FACTUAL ALLEGATIONS

A. THE SUBJECT DRUGS

19. The Pfizer Defendants manufacture, market, distribute and sell a number of prescription drugs for treatment of various forms of illnesses. These drugs include, but are not limited to, Geodon, Lyrica, Zyvox, Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zytec, Depo-Provera.

i. GEODON

20. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Geodon, a brand name prescription drug generically known as ziprasidone.

21. Geodon is one of a class of medications known as "atypical" or "second generation" antipsychotics ("SGA") that was initially approved for the treatment of acute manifestation of schizophrenia. Subsequently, Geodon was approved for the following limited uses as well:

a. *June 21st, 2002:* Approved for acute agitation in schizophrenic patients for whom treatment with ziprasdone is appropriate and who need intramuscular antipsychotic medication for rapid control of the agitation. (See FDA New Drug Application ("NDA") 020919).

b. *August 19th, 2004:* Approved for acute manic or mixed episodes in Bipolar I disorder; withor without psychotic features .(NDA 020825).

c. *March 29th, 2006:* Approval of Geodon (ziprasidone HCL). Oral suspension for the treatment of schizophrenia and for the treatment of acute manic or mixed episodes associated with bipolar disorder with or without psychotic features. (NDA 021483).

22. Geodon is only FDA approved for adult use and not for use by children. Upon information and belief, despite the limited approved indications for treatment with Geodon, Defendants promoted the drug for, *inter alia,* depression; bipolar maintenance; mood disorder' anxiety; aggression; dementia; attention deficit hyperactivity disorder; obsessive compulsive disorder; autism, posttraumatic stress disorder in unapproved patient populations including ***pediatric and adolescent patients***. Further, upon information and belief, the Defendants promoted Geodon in dosages that were above the maximum approved dosages.

23. Geodon received a black box warning due to increased mortality in elderly patients with dementia-related psychosis. It also slightly increases the OTc interval in some patients and increases the risk of a potentially lethal type of heart arrhythmia known as *torsades de pointes.*

24. Certain other drugs are often used with Geodon in order to help to control and/or manage Geodon's side effects. For example, Viagra helps to manage the neurochemical side effects and/or sexual dysfunction caused by psychiatric medications such as Geodon. Likewise, Zyrtec may also be used to counteract allergic signs and symptoms such as runny nose, sneezing, rash and itchy skin that can be due to treatment with Geodon.

25. There are many other "atypical anti-psychotics" that could be prescribed as alternatives to Geodon including, but not limited to, Abilify, Saphris, Clozaril, FazaClo, Fanapt, Zyprexa, Invega, Seroquel and Risperdal.

26. A key component of Pfizer's unlawful marketing with respect to Geodon was that the drug was as safe as or more effective than other antipsychotics and/or more tolerable because of Geodon's comparatively "safe" metabolic profile. However, that marketing of Geodon as comparatively safe and effective was deceptive and misleading and materially minimized and/or concealed Geodon's dangerous side effects. For example since FDA approval, Pfizer falsely marketed and promoted Geodon as a safer alternative to other antipsychotics including misleading advertisements representing that Geodon has minimal ability to cause neurological side-effects, when in fact it was known to Pfizer that Geodon produced neurological disorders known as Extrapyramidal Symptoms (EPS) in as many as 30% of those that take Geodon at the higher doses.

27. As stated above, Plaintiff, M.C., was prescribed Geodon for the treatment of ADHD during the period of at least 2003 through 2006. Because of Defendants' unlawful and unethical marketing and sales conduct, which included the "detailing" of Plaintiff's physician, Dr. Winters, by Pfizer sales representatives, Dr. Winters prescribed Geodon to Plaintiff for a period of approximately three years, despite the fact that Geodon is not an FDA approved treatment for ADHD, nor has FDA approved its use in children. When Dr. Winters initial prescribed Geodon to Plaintiff, he was only six years old. At first, Dr. Winters prescribed Geodon to Plaintiff in 10 mg doses. But when Plaintiff's condition did not improve, Dr. Winters increased Plaintiff's Geodon dosage to 20 mg. Thereafter, Plaintiff's condition still did not improve. After three years of futile treatment with Geodon, Plaintiff sought treatment from

another physician, Dr. Megan Douglas. Dr. Douglas discontinued Plaintiff's treatment with Geodon, and instead, prescribed over-the-counter melatonin. After Plaintiff began treatment with melatonin, his medical condition improved. Melatonin was not only much cheaper than Geodon, it was also more effective than Geodon at treating Plaintiff's medical condition.

28. Dr. Winters' practice focuses on psychiatric care of children and adolescents. Since Geodon is only FDA approved for treatment in adults, Dr. Winters would have no reason to prescribe Geodon to Plaintiff. However, Pfizer sales representatives induced Dr. Winters to prescribe Geodon to Plaintiff by providing her with financial incentives and misleading statements regarding Geodon's efficacy and treatment in children.

29. Upon information and belief, Pfizer sales representatives contacted Dr. Winters by various methods of communication and encouraged her to prescribe Geodon to children by misrepresenting the risk of neurological side effects caused by Geodon.

30. Upon information and belief, Pfizer sales representatives made false superiority claims about Geodon compared to competing products such as Ambilify and Zyprexa without any evidence to support such claims.

31. Upon information and belief, Pfizer sales representatives provided Dr. Winters with misleading promotional materials touting the effectiveness of Geodon in children. Specifically, representing the fact that Geodon has positive sedative qualities.

32. Upon information and belief, Pfizer paid Dr. Winters substantial honorariums to give "educational" lectures regarding Geodon in order to expand Geodon's off-label market share among pediatrics.

33. Upon information and belief, from January 1, 2001, through December 31, 2007, the exact dates are unknown to Plaintiff and the Class, the Pfizer Defendants illegally promoted

Geodon for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; made and disseminated unsubstantiated and false representations about the safety and efficacy of Geodon; and paid kickbacks to health care providers to induce them to prescribe Geodon.

ii. LYRICA

34. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Lyrica, a brand name prescription drug generically known as Pregabalin.

35. On December 30, 2004, Pfizer obtained approval from the FDA to market the prescription drug, Pregabalin, brand name Lyrica, for specific and limited uses. Specifically, the FDA approved Pregabalin for use in the treatment of diabetic peripheral neuropathy and postherpetic neuralgia. On June 13, 2005, the FDA approved Pfizer to market Pregabalin for the additional use of adjunctive treatment of partial onset seizures in adults with epilepsy. Doses for the FDA approved uses of Pregabalin are 50 mg/d to 600 mg/d. Pfizer thereafter began to market and promote the drug Pregabalin under the brand name LYRICA. Lyrica is also approved for the treatment of fibromyalgia. Upon information and belief, despite the limited approved indications for treatment with Lyrica, Defendants promoted the drug for, *inter alia,* chronic pain; neuropathic pain; perioperative pain and to treat migraines.

36. Lyrica, according to the clinical trials presented to the FDA by Pfizer, is a controlled substance and has been given a schedule V by the FDA as "potentially addictive". Because of its controlled substance status and addictive properties, Lyrica must have prescriptions written on a physician's green prescription pad, and is, as all controlled substances, strictly monitored by the D.E.A.

37. Common side effects of Lyrica include mild-to-moderate dizziness, sleepiness, blurred vision, dry mouth, swelling of the hands and feet and weight gain.

38. Neurontin is an alternative medicine that could be prescribed in lieu of Lyrica.

39. Certain other drugs are often used with Lyrica in order to help to control and/or manage Lyrica's side effects. For example, Viagra can be used to treat impotence and Zyrtec may also be used to counteract allergic signs and symptoms due to treatment with Lyrica.

40. After achieving FDA approval of Lyrica, Pfizer formed a scheme to maximize the sales of Lyrica. The overall scheme developed by Pfizer included the promotion of Lyrica for off-label uses and the promotion of Lyrica through unsubstantiated comparative studies concerning the efficacy of Lyrica versus other drugs that were then available

41. As noted above, once Lyrica was approved by the FDA for certain specific uses, Pfizer was prohibited by the Federal Food, Drug, and Cosmetic Act from marketing or promoting Lyrica for any off-label uses. It is further unlawful to market or promote a drug through the dissemination of false or misleading information, including unsubstantiated information regarding the safety and effectiveness of a drug.

42. The unlawful promotion of Lyrica was developed as a way to dramatically and rapidly increase the sale of Lyrica. By promoting Lyrica for off-label uses, Pfizer could expand the market for Lyrica, without the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses. By promoting Lyrica through the dissemination of unsubstantiated studies/reports, Pfizer could convert the users of competing drugs to Lyrica.

43. Accordingly, upon information and belief, from September 1, 2005, through October 31, 2008, the exact dates are unknown to Plaintiff and the Class, the Pfizer Defendants illegally promoted Lyrica, for uses not approved by the FDA and that were not medically-

accepted indications for which the U.S. and state Medicaid programs provided coverage; made and disseminated unsubstantiated and false representations about the safety and efficacy of Lyrica; and paid kickbacks to health care providers to induce them to prescribe Lyrica.

iii. ZYVOX

44. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zyvox, a brand name prescription drug generically known as linezolid. Zyvox is an Oxazolidinone Antibiotic, otherwise known as a synthetic antibacterial drug. The drug works by inhibiting bacterial protein synthesis at the initiation step and thereby preventing from multiplying and killing the bacteria.

45. Zyvox is approved by the FDA for treatment of vancomycin-resistant *Enterococcus faecium* infections; nosocomial pneumonia; community-acquired pneumonia and complicated skin and skin structure infections, including diabetic foot infections without concomitant osteomyelitis. Upon information and belief, despite the limited approved indications for treatment with Zyvox, Defendants promoted the drug for, *inter alia,* infections caused by methicillin-resistant *Staphylococcus aureus* ("MRSA") generally, rather than only those types for which Zyvox was FDA-approved.

46. Common side effects of short-term use of Zyvox include headache, diarrhea, and nausea. However, the side effects become more serious when Zyvox is used for longer duration, and include bone marrow suppression and low platelet counts, particularly when used for more than two weeks. Zyvox may also cause peripheral neuropathy, optic nerve damage and lactic acidosis.

47. Certain other drugs are often used with Zyvox in order to help to control and/or manage Zyvox's side effects. For example, Relpax is used to treat migrains and other headaches

and Zyrtex is an antihistamine which is used to treat rashes and/or allergic reactions due to treatment with Zyvox.

48. Zyvox is very expensive compared to antibiotics and is associated with a greater frequency of side effects. There are several other medications which can be prescribed as alternatives to Zyvox including but not limited to: Targocid, Vancomycin, Cefadroxil (Duracef), Amoxicillin/clavulante, Clarithromycin (Biaxin), Clindamycin (Cleocin), Doxycycline (Vibramycin), Fusid acid, Minocycline, Rifampin (Rifadin), Daptomycin (Cubicin) and Tigecycline (Tygacil).

49. Upon information and belief, from September 1, 2005, through October 31, 2008, the exact dates are unknown to Plaintiff and the Class, the Pfizer Defendants illegally promoted Zyvox for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; made and disseminated unsubstantiated and false representations about the safety and efficacy of Zyvox; and paid kickbacks to health care providers to induce them to prescribe Zyvox.

iv. DEPO-PROVERA

50. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Depo-Provera, a brand name prescription drug generically known as Depot Medroxyprogesterone acetate (DMPA).

51. Depo-Provera an injectable, contraceptive drug was approved by the FDA in October 1992 for use in women to prevent pregnancy. As an injectable, it is given once every three months and has been recommended for use as for long term birth control method, for example longer than two years if other birth control methods are inadequate.

52. Use of Depo-Provera estrogen levels and is associated with significant loss of bone mineral density (BMD) as bone metabolism accommodates to a lower estrogen level. While it has long been known that Depo-Provera causes bone loss, it has recently been discovered that the osteoporotic effects of the injection grow worse the longer Depo-Provera is administered, may remain long after the injections are stopped, and may be irreversible. For this reason, on November 17, 2004 the FDA and Pfizer agreed to put a "black box warning" on Depo-Provera's label.[1]

53. Many alternative contraceptives exist that can be prescribed to prevent pregnancy that are just as effective and with less serious side effects. Among the alternatives are: Seasonique, Ortho Tri- Cyclen, Ortho Tri-Cyclen Lo, Seasonale, and Loestrin 24Fe.

54. For years, Pharmacia, Pfizer's predecessor, trained and encouraged its district managers and sales representatives to "do deals" and "barter" with physicians and medical institutions by offering large quantities of drug samples (what Pfizer now calls "starters") in exchange for large or standing orders from the physicians and medical institutions for those or other drugs. This became an accepted practice that later resulted in Pfizer-trained District Managers and sales representatives exchanging large numbers of Pfizer-supplied Depo-Provera (an injectable contraceptive) samples (up to 100) in return for the physicians and medical institutions placing large Depo-Provera orders. To accomplish this, Pfizer sales representatives first promised physicians free sample doses of Depo-Provera, an injectable contraceptive, in exchange for the physicians purchasing Estring (FDA approved for treating various post-menopausal conditions). This bartering continued thereafter, without Estring, which illegally manipulated Medicaid "best price" and "average manufacturer price" reimbursement and rebate

[1] *"'Black box' warning added to contraceptive injection"*. FDA Consumer., March-April 2005, available at, http://findarticles.com/p/articles/mi_m1370/is_2_39/ai_n14727066/ last visited, February 10, 2010.

calculations. The deals drastically decreased the average wholesale price per dose paid and reimbursed the physicians at an artificially higher rate. This practice also improperly influenced physicians' decisions about whether to prescribe Depo-Provera, so that patients receiving those drugs could not be certain that their treatment was guided solely by their physicians' independent medical assessment of their diagnoses.

v. ARICEPT

55. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Aricept, a brand name prescription drug generically known as donepezil. Aricept is an acetylcholinesterase inhibitor that inhibits activity of the enzyme responsible for the breakdown of acetylcholine; therefore, increasing acetylcholine levels. A deficiency of acetylcholine is thought to be the cause of Alzheimer's disease

56. Aricept was approved by the FDA in November 1996 for the symptomatic treatment of mild to moderate Alzheimer's disease. In 2006, Aricept was approved for the treatment of severe Alzheimer's disease, becoming the first and only prescription to treat the full spectrum of Alzheimer's disease.

57. Since depression often accompanies Alzheimer's disease, Aricept and Zoloft may be prescribed together. They are therefore known as "companion drugs" which are meant to augment rather than replace each other in treatment.

58. Alternative medications that may be used in lieu of Aricept to treat Alzheimer's include Exelon, Razadyne and Namenda.

59. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker

programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Aricept.

vi. LIPITOR

60. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Lipitor, a brand name prescription drug generically known as atorvastatin. Lipitor is an Anti-Lipid that inhibits an enzyme used by the body in the production of cholesterol.

61. Lipitor was approved by the FDA in December 1996 to reduce elevated LDL-cholesterol. In 2007, the FDA approved Lipitor to be used as treatment to aid the prevention of nonfatal heart attacks, as well as fatal and nonfatal strokes.

62. Certain other drugs are often used with Lipitor including Aricept which may be used together in patients treating for Alzheimer's disease off label with Lipitor. Likewise, other medications may be used in order to help control and/or manage Lipitor's side effects. For example, Zyrtec is often used to treat allergic signs and symptoms such as rash and/or runny nose that may be due to treatment with Lipitor.

63. Alternative statin medications that may be prescribed in lieu of Lipitor include Zocor, Mevacor, Pravachol, Crestor and others.

64. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Lipitor.

vii. RELPAX

65. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Relpax, a brand name prescription drug generically known as eletriptan. Relpax is an anti-migraine agent that reduces the swelling of blood vessels surrounding the brain. Relpax blocks the release of substances from nerve endings that cause pain, nausea and sensitivity to light and sound.

66. Relpax was approved by the FDA in December 2002 for the acute treatment of migraine headaches, with or without aura, in adults.

67. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Relpax.

viii. VIAGRA

68. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Viagra, a brand name prescription drug generically known as sildenafil. Viagra is an impotence drug that causes smooth muscle relaxation and flow of blood to the erectile tissue of the penis.

69. Viagra was approved by the FDA in 1998 to treat erectile dysfunction.

70. Alternative medications that may be used in lieu of Viagra include Levitra and Cialis.

71. Certain other drugs are often used with Viagra including any SSRI medication or other medications that are known to cause impotence such as Geodon and Zoloft. Likewise, certain other drugs are often used with Viagra in order to help to control and/or manage Viagra's

side effects. For example, Relpax may be used to counteract a headaches potentially caused by the dilution of vessels from treatment with Viagra. Likewise, Zyrtec may be used to treat rashes caused by treatment with Viagra.

72. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Viagra for treatment in women.

ix. ZITHROMAX

73. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zithromax, a brand name prescription drug generically known as azithromycin. Zithromax is an antibiotic that blocks the production of a certain type of protein in bacterial cells, thus, limiting growth.

74. Zithromax was approved by the FDA in 1992 for adults to treat infections caused by bacteria, such as respiratory infections, skin infections, and ear infections. In 1995, Zithromax was approved for use in children.

75. discussed below, Zithromax may be used off label to treat medication induced gingival hyperplasia caused by treatment with Norvasc.

76. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Zithromax.

x. NORVASC

77. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Norvasc, a brand name prescription drug generically known as amlodipine. Norvasc is an anti-hypertensive that blocks calcium channels in the blood vessels and heart, preventing contraction of blood vessels and allowing them to widen and relax. It dilates blood vessels and slows the heart to reduce blood pressure and angina pain.

78. Norvasc was approved by the FDA in July 1992 to treat high blood pressure and angina.

79. Alternative medications/additional channel blockers that may be prescribed in lieu of Norvasc include Cardizem, Dilcor and others (diltiazem), Plendil (felodipine), DynaCirc (isradipine), Cardene, Cardene SR (nicardipine), Adalat cc, Procardia XL (nicardipine), Calan, Isoptin and others (verapamil).

80. Certain other drugs are often used with Norvasc in order to help to control and/or manage Norvasc's side effects. For example, Zithromax may be used to treat medication induced gingival hyperplasia, Zyrtex may be used to treat skin rash or itching, Relpax may be used to treat headaches, Zoloft may be used to treat depression symptoms and Viagra may be used to treat impotence, all of which could be caused by treatment with Norvasc.

81. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Norvasc.

xi. ZOLOFT

82. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zoloft, a brand name prescription drug generically known as sertraline. Zoloft is an anti-depressant (Serotonin reuptake inhibitor - SSRI) that inhibits the reuptake of serotonin at the neuron; thus, increasing levels of serotonin in the body and in the brain.

83. Zoloft was approved by the FDA in 1991 for the treatment of depression. In February 2003, Zoloft was approved by the FDA for acute and long-term treatment of social anxiety disorder.

84. Generic Zoloft is available through several companies under the name "Sertraline".

85. Certain other drugs are often used with Zoloft in order to help to control and/or manage Zoloft's side effects. For example, Viagra may be used to counteract ejaculatory disturbances and decreased libido which may be caused by treatment with Zoloft. Likewise, Relpax may be used to treat migraine side effects which may be caused by treatment with Zoloft.

86. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Zoloft.

xii. ZYRTEC

87. The Pfizer Defendants, at certain times during the relevant time period, manufactured, distributed, promoted, marketed and/or sold Zyrtec, a brand name prescription

drug generically known as cetirizine. Zyrtec is an antihistamine which selectively inhibits peripheral H1 receptors.

88. Zyrtec was approved by the FDA in 1996 for the treatment of allergies, hay fever, angioedema and urticaria.

89. Certain other drugs are often used with Zyrtec including any medication that is known to cause anaphylaxis, allergy or rash could potentially be used with Zyrtec. Likewise, certain other drugs are often used with Zyrtec in order to help to control and/or manage Zyrtec's side effects. For example, Viagra may be used to counteract a decrease in libido caused by treatment with Zyrtec.

90. Upon information and belief, from January 1, 2001, through December 2004, the exact dates are unknown to Plaintiff and the Class, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs and gifts including entertainment, cash, travel, and meals to health care professionals to induce them to promote and prescribe Zyrtec.

B. BACKGROUND ON PFIZER MARKETING AND SALES PRACTICES

91. Marketing and advertising its drugs to consumers as well as physicians has been critical to Pfizer's success. Pfizer collects detailed information regarding the behavior of prescribing doctors, the number of prescriptions, and the general usage for which those prescriptions were written with respect to its own drugs and for competitor drugs. This is commonly referred to as "prescription data mining." *Dr. Drug Rep.,* Daniel Carlat, N.Y. Times Magazine (Nov. 25, 2007). Among Pfizer's purposes for prescription data mining is the identification of doctors who are supportive of Pfizer drugs over competitors' drugs and who may be incentivized to convince other doctors to prescribe Pfizer drugs as well. Within Pfizer, this identification process was at times referred to as "influence mapping." In essence, Pfizer

collects extensive data for the specific purpose of targeting physicians likely to be susceptible to unlawful off-label promotion of Pfizer pharmaceuticals.

92. Pfizer employs and trains numerous "pharmaceutical sales representatives" ("sales reps" or "PSR's") to visit and persuade identified doctors to prescribe Pfizer drugs to patients. Doctors understand that Pfizer sales reps visit them to promote Pfizer drugs. Certain doctors, including many of whom Pfizer has identified through the influence mapping process as "thought leaders" or "key opinion leaders," who refuse to meet with sales reps. Pfizer therefore also employs medical liaisons or "regional medical and research specialists" ("RMRS"). As explained in an October 20, 2009 job advertisement in the New Scientist, Pfizer medical liaisons are expected to "establish relationships with regional and national [Key Opinion Leaders], medical leaders in the regions including academicians, medical directors, directors of pharmacy and other health care professionals."

93. Using the information collected via Pfizer's marketing efforts, including prescription data mining, influence mapping, and the employment of sales reps and medical liaisons, Pfizer formulates multi-billion dollar marketing and promotion budgets and strategic plans that are approved by the highest levels of management. Pfizer has one of the largest advertising budgets in the United States. These budgets include hundreds of millions of dollars to organize or sponsor meetings with doctors, teleconferences, advisory panels, and continuing medical education seminars. In addition, Pfizer uses information gathered through their marketing efforts such as prescription data mining, influence mapping, sales representatives and medical speakers in formulating multi-billion dollar marketing budgets. The budgets allocate hundreds of millions of dollars to sponsor direct meetings with doctors, advisory panels, and CME seminars.

C. PFIZER'S UNLAWFUL SALES AND MARKETING STRATEGY

94. Before and during the Relevant Period, Defendants knowingly caused and/or permitted a Company-wide, multifaceted strategy to promote off-label prescriptions for numerous Pfizer drugs through illegal off-label marketing and payment of illegal kickbacks, including for Aricept, Geodon, Lipitor, Lyrica, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zyrtec, Depo-Provera and Zyvox.

95. Using the nationwide information from "prescription data mining" efforts and the results from "influence mapping" analyses, Defendants caused Pfizer to select specific doctors to be targeted for Pfizer's marketing efforts encouraging off-label prescribing behavior. Selected doctors would be visited by Pfizer's sales reps, who were provided with specific prescription quotas for doctors within their geographic territory. As former Pfizer sales rep Mark Westlock explained in a sealed whistleblower complaint,[2] the quotas provided by Pfizer's headquarters included doctors whose practices did not typically give rise to a need to prescribe the promoted drugs for FDA-approved uses.[3] Moreover, according to Westlock, Pfizer's sales reps, district managers, regional managers, and vice-presidents of sales all had a financial incentive to maximize prescribing behavior without regard to whether prescriptions were on-label or off-label.[4] In order to influence prescribing behavior and assist Pfizer's sales force in promoting off-label prescriptions, numerous free samples of the Company's drugs were provided for distribution to doctors, including to doctors who had no FDA-approved use for the drug. Former Pfizer sales representative and "institutional health representative" Blair Collins and former

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[2] Unless otherwise indicated, the whistleblower complaints referenced herein were only recently unsealed.

[3] Complaint, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et a*l., Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

[4] *Id*. at ¶¶217-222.

Pfizer sales representatives John Kopchinski, David Farber, Casey Schildhauer, all detailed this prevalent practice in their whistleblower complaints.[5]

96. Before and during the Relevant Period, the Company's own medical liaisons (or RMRSs) assisted Pfizer's sales force with promoting off-label prescriptions. In a sealed whistleblower complaint, former Pfizer district manager Ronald Rainero explained that Pfizer had developed a marketing scheme known as the "Scientific Ambassador Program" in which "Pfizer scientists are used to promote Pfizer drugs off-label and to enable representatives to gain access to difficult to influence physicians."[6] According to Rainero, Pfizer's senior sales management received bonuses predicated on the number of Scientific Ambassador programs implemented in their region.[7] Whistleblowers David Farber, Casey Schildhauer and Mark Westlock similarly confirmed the use of Pfizer's medical liaisons to promote off-label prescriptions in their complaints.[8]

97. Indeed, this strategy—using Pfizer's own purportedly independent scientists to manipulate the prescription habits of physicians—was a global effort. In 2002, the *British Medical Journal* reported, for example, that Pfizer had been given a "rare public reprimand" by the Association of the British Pharmaceutical Industry because the British Prescription Medicines Code of Practice Authority, which monitors complaints about drug companies, had

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[5] *See* Complaint at ¶45, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007); Complaint at ¶¶111-13, *United States ex rel. John Kopchinski v. Pfizer, Inc. et al*., Civ. No. 05-cv-12115 RCL (D. Mass. Dec. 12, 2008).

[6] Complaint at ¶¶20, 180, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).

[7] *Id*. at ¶179.

[8] Complaint at ¶127, *United States ex rel. David Farber and Casey Schildhauer v. Pfizer, Inc*., Civ. No. 07-10304 (D. Mass. June 12, 2007); Complaint at ¶184, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

discovered that "Pfizer had been using a team of medical liaison executives to promote unlicensed medicines and to promote off-license indications for other products."[9]

98. During their visits with targeted doctors, Pfizer's sales reps and medical liaisons would habitually make false and misleading statements about the available evidence regarding the safety and/or efficacy of off-label prescriptions with respect to specific Pfizer drugs. For example, former Pfizer sales rep Robert Liter stated in a sealed whistleblower complaint that during a national sales meeting in September 2005, "Pfizer instructed and encouraged me and other sales representatives to employ the following illegal promotional tactics to promote the sale of Lyrica". . . [m]aking false statements to physicians and pharmacists concerning the efficacy and safety of Lyrica for 'off-label' uses" and "[a]ctively concealing its promotional scheme from the FDA to avoid that agency's enforcement mechanisms."[10] Former Pfizer sales representatives Wetherholt, Dimer and Westlock independently substantiated Liter's account in other whistleblower complaints.[11]

99. Defendants intentionally supported Pfizer's sales force and medical liaisons in making such false and misleading statements by commissioning articles in medical journals that ostensibly supported off-label prescriptions of Pfizer drugs and by distributing such articles to its sales force.

100. Former Pfizer sales representative Glenn DeMott explained that Pfizer's sales force would receive the biased studies that were commissioned and funded by Pfizer for

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[9] *See* BMJ 2002 March 30; 324(7340): 753, *available* at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1122697//, last viewed on November 7, 2009.

[10] Complaint at ¶32, *United states ex rel. Robert A. Liter v. Pfizer, Inc.*, Civ. No. 06-176 WOB (E.D. Ky. Nov. 21, 2007).

[11] *See* Complaint at ¶27, *United States ex rel. David Wetherholt and Marci Dimer v. Pfizer, Inc.*, Civ. No. 06-10240-DPW, (D. Mass. Feb. 2, 2006); Complaint at ¶, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

distribution among prescribing doctors to promote off-label prescriptions.[12] According to John Kopinchski's whistleblower complaint, this practice was a "cornerstone" of Pfizer's marketing strategy.[13]

101. Pfizer's sales force also was provided with substantial financial means to promote off-label prescribing behavior. As explained by former Pfizer sales representative John Kopchinski in his whistleblower complaint, doctors who were identified as suitable marketing targets would, for example, be invited for "consultant meetings" and were "frequently paid money to attend on the pretence that they would provide 'consulting information.'"[14] According to Kopchinski, hundreds of such consultant meetings were organized across the country, to which between fifty and several hundred doctors would typically be invited and paid to attend.[15] Kopchinski reported that, in addition to travel expenses and accommodations in luxury hotels, physician participants were paid "between $250 and $1500 each to simply attend a single consultant meeting" and that they were typically "not required to do anything but show up to receive his or her payment."[16] According to Kopchinski, these conferences were simply pretexts for paying unlawful kickbacks.[17]

102. In addition to paying doctors to attend Pfizer's marketing meetings, Defendants also caused doctors, including identified key opinion leaders, to be paid to speak at ostensibly "independent" continuing medical education meetings, roundtables and other meetings with colleagues to promote off-label prescribing behavior for Pfizer drugs. According to

[12] Amended Complaint at ¶4, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).
[13] Complaint at ¶103, *United States ex rel. John Kopchinski v. Pfizer, Inc. et al.,* Civ. No. 05-CV-12115 RCL (D. Mass. Dec. 12, 2008).
[14] *Id*. at ¶114.
[15] *See Id.* at ¶124.
[16] *Id.* at ¶125
[17] *Id.*

whistleblower Westlock, "Pfizer recruited a nationwide network of paid speakers to promote Geodon, maintained lists of these speakers, tracked each speaker's effectiveness, including each speaker's off-label presentations, and provided these lists to its sales force."[18] One of those speakers was reportedly paid up to $4, 000 per day plus expenses and "became such a frequent speaker that he used his own private helicopter to fly to various locations throughout the United States, all at Pfizer's expense."[19] Whistleblowers Glenn DeMott, David Farber, Casey Schildhauer, (all former Pfizer PSRs) and Stefan Kruszewski (a board-certified physician) confirmed Pfizer's use of paid medical speakers to promote off-label prescriptions in their complaints.[20]

103. Defendants carefully tracked their investment in encouraging off-label prescriptions in the form of number of prescriptions and revenues. According to Collins, this was accomplished by the use of accounting software called the "Budgets and Education Tracking System" or "BETSY" and, based on this tracking, "Pfizer expected to get a $10 return on investment (i.*e.,* sale of its drugs) for every $1 spent through marketing budgets."[21]

104. In his whistleblower complaint, Mark Westlock stated, for example, that he was the subject of retaliation after he informed defendant Read (Pfizer's Worldwide Pharmaceuticals Operations President and a member of Pfizer's Executive Leadership Team) and other members of Pfizer's management in 2007 of the illegal off-label promotion of Geodon. Retaliation from the upper levels of Pfizer in response to reports of wrongdoing was so frequent and so widely

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[18] Complaint at ¶160, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[19] *Id.* at ¶165.
[20] *See* Complaint at ¶42, *United States ex rel. David Farber and Casey Schildhauer v. Pfizer, Inc.,* Civ. No. 07-10304 (D. Mass. June 12, 2007): Complaint at ¶92, *United States ex rel. Steven Kruszewski v. Pfizer, Inc.,* Civ. No. 07-CV-4106 (E.D. Pa. Aug. 21, 2009).
[21] Complaint at ¶43, 150, *United States ex rel. Blair Collins, et al., v. Pfizer, Inc.* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

known among Pfizer employees that they invented an acronym to describe it. As explained in the government's October 9, 2009 sentencing memorandum in the criminal action involving the illegal marketing of Bextra (discussed in more detail in Section IV.F, *infra*), to report illegal off-label marketing to senior management was "considered a 'CLM' or 'Career Limiting Move', "that is "an action that possibly ended his/her promotion potential or led to being disfavored by management and, ultimately fired."

i. 2002 – Pfizer Pays a Multimillion Dollar Settlement and Accepts the First Corporate Integrity Agreement

105. Lipitor is a medication that reduces low-density lipoprotein cholesterol and overall cholesterol in the blood. Lowering cholesterol can help prevent heart disease, strokes and vascular disease. Financially, Lipitor has been one of Pfizer's most successful drugs, ranking among the world's most profitable drugs of the past decade.

106. In 2002, Pfizer subsidiary Warner Lambert settled charges under the civil False Claims Act alleging that, prior to its 2001 acquisition by Pfizer, it had illegally concealed cash discounts given to a managed care organization in New Orleans called the Ochsner Health Plan ("Ochsner"). In exchange for these concealed discounts, Ochsner agreed to extend an unlawful *quid pro quo* in the form of an "unrestricted formulary status to Lipitor in order to encourage Ochsner plan doctors to write Lipitor prescriptions for Ochsner plan beneficiaries," meaning that doctors who were part of the Ochsner plan knew that there were few restrictions on plan coverage for Lipitor prescriptions. As a result of the illegal non-disclosure of those discounts, Warner Lambert was alleged to have retained $20 million in Medicaid rebates that it owed to the Medicaid program. Although prior to the acquisition by Pfizer, this misconduct took place under the auspices of a Lipitor marketing agreement between Pfizer and its soon-to-be subsidiary Warner Lambert.

107. To settle the charges that Warner Lambert had improperly overcharged the Medicaid program, Pfizer agreed to pay $49 million. In addition, Pfizer entered into a five-year corporate integrity agreement (the "2002 CIA") with the Office of the Inspector General of the Department of Health and Human Services ("OIG HHS") to ensure that Pfizer would not pay illegal kickbacks in the future. Under the 2002 CIA, the Board was required to directly preside over a compliance mechanism designed to elevate information concerning legal compliance or non-compliance directly to the Board.

a) Pfizer's Obligations Under The 2002 CIA

108. As noted above, as a result of the 2002 and 2004 settlements, Pfizer was required to implement "Corporate Integrity Agreements" mandating, among other things, the creation of an internal compliance mechanism specifically designed to report and evaluate any non-compliance issues directly to the Board.

109. The 2002 CIA was signed on October 24, 2002 by various Pfizer lawyers, including by Pfizer deputy corporate compliance office defendant Lankler. In the preamble, Pfizer represented that it had already voluntarily implemented compliance measures, including "the appointment of a Compliance committee, a Disclosure Program . . . and regular training" of "all employees of the Pfizer Pharmaceuticals Group located in the United States whose job responsibilities directly related to the promotion of prescription drug products to managed care facilities" and "those persons of Pfizer's contract sales force whose job responsibilities directly related to Managed Care Contracting."

110. The 2002 CIA required Pfizer to "implement written policies and procedures regarding the operation of Pfizer's Compliance Program, and its compliance with Federal health care program requirements." Those policies and procedures were required to address, among

other things, "promotional practices that conform with all applicable Federal health care program requirements, including but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b."

111. The 2002 CIA also required the Company to establish an internal mechanism for directly reporting compliance violations to the Board and required active involvement by the Board in policing Pfizer's compliance with the FDCA and the Federal anti-kickback statute. For example, the 2002 CIA specifically required Pfizer's Compliance Officer ***"make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and shall be authorized to report on such matters to the Board of Directors any time."*** From 2002 until his appointment as Pfizer's Chief Executive Officer in 2006, Kindler was the "Compliance Officer" who had the obligation to make those periodic (at least semi-annual) reports to the Board.

112. Documents prepared by Pfizer personnel show the clear understanding of Pfizer's senior management and the Board that the 2002 CIA required the Board to be actively involved in policing Pfizer's compliance with the FDCA and the Federal anti-kickback statute. For example, on June 9, 2003, defendant Lankler gave a presentation at the 2003 Pharmaceutical Congress entitled "Living With a Corporate Integrity Agreement" that included bullet points stating: "***Make sure everyone knows about the CIA and understands its impact," "Frequent reminders," "Involve Board; keep them involved," and "Document everything."***

ii. 2004 - Pfizer Pays The Second Largest Criminal Fine Ever Imposed In A Healthcare Fraud Prosecution And Enters Into Another Corporate Integrity Agreement

113. Neurontin is an anticonvulsant medication that affects chemicals and nerves in the body that causes seizures. In the U.S., Neurontin is manufactured and sold by Warner Lambert, a wholly-owned subsidiary of Pfizer.

114. The FDA approved the use of Neurontin for the management of post-herpetic neuralgia (pain resulting from damage caused by shingles or herpes zoster) in adults and to control epileptic seizures of adults if used in conjunction with another drug. The FDA approved doses ranging from 900 mg to 18 mg per day. Neurontin is a drug with dangerous side effects, even when it is administered for an approved use and at an approved dosage.[22]

115. In 1997, Warner Lambert formally applied to the FDA to change Neurontin's labeling to include a stand-alone treatment (*i.e.*, treatment without simultaneous use of other medication or "mono-therapy") for epilepsy seizures. The FDA rejected this application and declined to approve the prescription of Neurontin for use as a general pain medication or for the treatment of bipolar disorder, depression, migraine, or attention deficit disorder. Warner Lambert nevertheless began to promote Neurontin for off-label uses and dosages, without knowing whether it was medically safe to do so, for: (i) off-label dosages exceeding 1800 mg per day; (ii) use as an epilepsy monotherapy; (iii) use as a general pain medication; and (iv) use as a treatment of bipolar disorder, depression, migraine, and attention deficit disorder.

116. On May 19, 2003, a former medical liaison of Warner Lambert, Dr. David Franklin, filed a whistleblower lawsuit under the federal civil False Claims Act and a sworn

[22] On January 31, 2008, the FDA sent out an alert entitled "Serious Health Risks with Antiepileptic Drugs" to alert health care professionals and consumers that a reviews of 11 antiepileptic drugs studies showed that patients taking anti-epileptics such as Neurontin "have about twice the risk of suicidal thoughts and behaviors, compared with patients receiving an inactive substance (placebo)."

affidavit detailing the illegal off-label marketing strategy, including how medical liaisons were "trained and instructed to misrepresent the amount of clinical evidence available to support the use of Neurontin" and to "ignore and conceal any negative information about Neurontin." Warner Lambert's promotion campaign showed blatant disregard for the safety or legality of its drug sales. The Associate Director of Medical Affairs for the Northeastern region of the United States was quoted as instructing medical liaisons who visited doctors to promote Neurontin for off-label uses as follows:

> Medical liaisons, this is Phil. I am calling in regard to the – you know, there's a Neurontin push that's supposed to be on. What we'd like to do is, anytime you're called out, just make sure that your main focus out of what you are doing is on Neurontin….When we get out there, we want to kick some ass on Neurontin, we want to sell Neurontin on pain. All right? **And monotherapy and everything we can talk about, that's what we want to do.**

117. Dr. Franklin further described in his affidavit that he was "trained and instructed to use a number of misleading abstracts and case reports" to promote Neurontin for "a variety of medically unacceptable uses." According to Dr. Franklin, Pfizer's subsidiary also trained medical liaisons like himself to make offers of paid consultancy engagements, offers of paid participation in "studies," offers of junkets to first class resorts or hotels paid for by Warner Lambert, and offers of cash payments in order to induce physicians to prescribe Neurontin for off-label uses, and a higher doses than approved by the FDA.

118. Following the submission of Dr. Franklin's affidavit, the federal government opened a criminal investigation. In 2004, Warner Lambert pled guilty to criminal and civil charges that it had fraudulently promoted the uses of Neurontin to treat a wide array of ailments for which the drug was not approved, in violation of the FDCA. As the DOJ noted on May 15, 2004, Pfizer's subsidiary "promoted Neurontin even when scientific studies had shown it was not effective."

119. In the government's June 2, 2004 sentencing memorandum, the prosecutor set out a number of "key tactics" that were used to increase off-label use of Neurontin, including: (i) "Encouraging sales representatives to provide one-on-one sales pitches ('details') to physicians about off-label uses;" (ii) "Utilizing medical liaisons, who represented themselves, often falsely, as neutral scientific experts in the area of a particular drug, to promote off-label uses for Neurontin, working in tandem with sales representatives;" (iii) "Paying physicians, through both direct payments, and the provisions of trips, hotel rooms, dinners and other benefits, to attend a variety of 'consultant' or 'advisory' meetings or 'speaker bureau trainings' in which doctors received presentations about off-label uses of Neurontin;" and (iv) "Sponsoring ostensibly independent medical education' events of off-label Neurontin uses . . ."[23] In calculating the culpability score, the sentencing memorandum noted that this marketing scheme **was implemented with knowledge and approval of senior management.**[24] According to the DOJ May 15, 2004 release, "**[*t*]hese tactics were part of a widespread, coordinated national effort** to implement an off-label marketing plan."

120. To settle the charges, Pfizer's subsidiary pled guilty to two felony counts of violating the FDCA and Pfizer agreed to pay a $240 million criminal fine. The DOJ explained at the time that this fine was **"the second largest criminal fine ever imposed in a health care fraud prosecution."** Pfizer agreed to pay an additional $190 million to resolve related claims under the civil False Claims Act, including allegations of violations of the Federal anti-kickback statute, that Warner Lambert's conduct had caused doctors to write prescriptions for Medicaid patients when those medications were not eligible for Medicaid reimbursement because those

[23] *See* United States' Sentencing Memorandum to the Federal District Court of Massachusetts, 26-27, *United States v. Warner Lambert Company LLC*, Case Number 04-CR-10150 RGS (D. Mass. June 2, 2004).
[24] *Id.* at 51

prescriptions were fraudulently obtained through false statements to doctors and by payments of illegal kickbacks, including so-called "consulting fees" and paid trips for doctors.

121. In addition to paying the then-second largest criminal fine ever imposed in a health care fraud prosecution and millions of dollars in civil fines to atone for past transgressions, Pfizer also entered into another, more extensive corporate integrity agreement to prevent similar practices in the future (the "2004 CIA"). Once again, the Board was at the center of the compliance obligations imposed by the 2004 CIA. The 2004 CIA again required the Board to directly preside over a mechanism designed to elevate information concerning legal compliance or non-compliance directly to the Board, and, in addition, placed significantly more stringent obligations on the Board than the 2002 CIA. The DOJ itself stated on May 15, 2004 its expectation and understanding that the 2004 CIA would ensure that "any future off-label marketing conduct is detected and corrected on a timely basis."

a) Pfizer's Obligations Under the 2004 CIA

122. As with the 2002 CIA, the 2004 CIA was signed by Pfizer deputy compliance officer Defendant Lankler and required the establishment of mechanisms to ensure direct reporting to senior management and the Board concerning compliance or non-compliance with the FDCA, the Federal anti-kickback statute, and Federal health care program requirements. The 2004 CIA required Pfizer to maintain a disclosure program to enable employees to report violations of Federal health care law and FDA regulations to senior management and the compliance department. It further required the Compliance Officer to maintain a disclosure log to record a summary of each received disclosure, the status of any review, and any corrective action taken in response. The disclosure program was required to "emphasize a nonretribution,

nonretaliation policy" and to "include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained."

123. The 2004 CIA emphasized the required monitoring and oversight role of the Board in ensuring that Pfizer would not again engage in illegal marketing and sales promotions of its drugs. It provided that Pfizer's Chief Compliance Officer and Pfizer's Deputy Compliance Officer "shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and both shall be authorized to report on such matters to the Board of Directors at any time." The 2004 CIA required that "these periodic reports" inform "the Directors . . . of Pfizer's continuing activities and obligations under the [2004 CIA]."

124. The 2004 CIA also noted that "the Directors have agreed to abide by a Code of Conduct which they adopted." As described above, the Code of Conduct and Ethics required the Board, among other things, to "comply, and oversee compliance by employees, officers and other directors, with laws, rules and regulations applicable to the Company." The 2004 CIA further required "all officers directly involved in Pfizer's U.S. Pharmaceutical operations" to certify that they "read, received, understood and shall abide by Pfizer's [Code of Conduct and Ethics]," including the requirement that they would be "expected to comply with all Federal health care program requirements and FDA requirements."

125. Defendants also agreed to implement written policies and procedures regarding the operation of Pfizer's compliance program and that those policies would, among other things, address:

> (i) The methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all FDA requirements;

(ii) Policies designed to ensure that speaker meetings, advisory board meetings and all other consulting arrangements would be used for legitimate purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about off-label uses of products;

(iii) Policies designed to ensure that Pfizer's sponsorship or funding of grants, research or related activities (including clinical trials, market research or authorship of other articles) comply with all applicable Federal health care program and FDA requirements; and

(iv) The methods for selling, marketing, and promoting Pfizer products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute.

iii. 2007 - Pfizer Pays Yet Another Criminal Fine for its Illegal Promotion and Sales practices Related to Genotropin

126. Genotropin is a human growth hormone (anabolic steroid) that was approved by the FDA for the limited use of treating children who suffer from growth failure. In the U.S., Genotropin is manufactured and sold by Pharmacia, a wholly-owned subsidiary of Pfizer. Genotropin can pose substantial risks to human health, particularly for teenagers, when it is prescribed for off-label uses or dosages. In the August 2004 edition of "Endocrine News," Dr. Linn Goldberg of the Hormone Foundations' Hormone Abuse Program Advisory Council noted for example that "[y]oung developing bodies are likely more sensitive to the ***adverse health effects of steroids, some of which can be irreversible*** such as the stunting of height in males and voice and body/facial hair changes in females."

127. The FDCS also recognizes the substantial health risks posed by the use of human growth hormones like Genotropin for uses that are not approved by the FDA. Under the provisions of this statute, whoever knowingly distributes or possesses with intent to distribute human growth hormones for any use that is not approved by the FDA faces up to 5 years in prison, and up to 10 years in prison if the offense involves a minor.

128. Pfizer subsidiary Pharmacia did not seek approval from the FDA for use of Genotropin for athletic performance enhancement, anti-aging, or cosmetic use. Pharmacia also did not submit information to the FDA asserting that such other uses would be safe, and the FDA never approved such other uses. Knowing that it was illegal to do so, and with the intent to defraud and mislead, Pharmacia nevertheless marketed Genotropin for unapproved uses, including athletic performance enhancement, anti-aging, and cosmetic use.

129. The illegal off-label marketing and sales promotion of Genotropin was very successful—Pfizer's revenues from Genotropin increased from $481 million in 2003 to $843 million in 2007.[25] Similarly, the August 2004 edition of "Endocrine News" noted that a number of national studies had concluded that during 2001, when Pharmacia had already begun its efforts to illegally market the off-label use of Genotropin, "lifetime use of anabolic steroids was at a new high of 3.7 percent among 12th graders."

130. In or about March 2007, Pharmacia entered into criminal guilty plea for the illegal promotion and sales practices of Genotropin. Pfizer's subsidiary admitted that during visits to anti-aging doctors and clinics, "Pharmacia made misleading representations about the effectiveness of Genotropin as an anti-aging medication," that it "knew it was illegal to promote Genotropin for Unapproved Uses such as anti-aging," and that it had "earned millions of dollars in gross revenue from selling Genotropin for various Unapproved Uses." Moreover, Pfizer's subsidiary admitted that "[s]ome of the reasons that individuals took Genotropin had nothing to do with any medical condition, but instead were to obtain better skin tone, better skin elasticity, better general appearance, and better ability to lift more weights at the gym."

[25] *See* Pfizer Form 10-K for 2003 *and* Pfizer Form 10-K for 2007 filed with the U.S. Securities and Exchange Commission.

131. In or about March 2007, Pharmacia also pleaded guilty to intentionally violating the Federal anti-kickback statute. Pharmacia admitted that it had knowingly and willfully offered excess payments on a contract with a drug distribution company to induce that company into recommending purchasing or ordering Pharmacia's pharmaceutical products that were eligible for payment under a Federal health care program.

132. To settle the charges regarding the illegal promotion and sales practices of Genotropin and the charges related to the Federal anti-kickback statute, Pfizer entered into a deferred prosecution agreement with the U.S. Attorney's Office in Massachusetts. In addition, Pfizer agreed to pay $34.6 million in criminal fines.[26]

iv. **The Reporting of Non-Compliance and Violation of the Relevant Pharmaceutical Marketing Laws, Pursuant to the Various CIA's Leading Up to the 2009 Fine**

133. As discussed above, the 2002 and 2004 CIAs contained extensive reporting requirements to make senior management and the Board aware of non-compliance with and violation of the relevant drug marketing laws. Between 2002 and April 2009, Pfizer's Chief and Deputy Compliance Officers thus informed the Compliance Committee, the Audit Committee and other members of the Board repeatedly of allegations to that numerous Pfizer employees were violating the FDCA, FDA regulations, Federal healthcare program regulations and the Federal anti-kickback statute with regard to numerous drugs. Among other red flags, Pfizer's Chief and Deputy Compliance informed the Compliance Committee, the Audit Committee and other members of the Board of over twenty FDA Warning letters regarding Pfizer's off-label promotion of the Subject Drugs as well as notices to cease misleading advertising of the subject drugs due to unsubstantiated and/or false statements.

[26] The criminal fine consisted of $15 million for the illegal promotion and sales practices of Genotropin and $19.6 million for intentional violations of the Federal anti-kickback statute.

v. September 2009- The Government Imposes History's Largest Criminal Fine and Largest Civil Fine for Any Healthcare Fraud

134. On September 2, 2009, the Department of Justice ("DOJ") announced that the largest Health Care Fraud Settlement in its History was reached with Defendants Pfizer and Pharmacia. Pfizer and its subsidiary Pharmacia & Upjohn Co., Inc., agreed to pay $2.3billion to resolve criminal and civil liability arising from the illegal promotion of the Subject drugs, as well as another drug, Bextra. The investigation was triggered by the filing of several Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, whose prosecution and litigation was handled by the U.S. Attorney's offices for those Districts as well as the Civil Division of the Department of Justice.

135. The Settlement resolved past off-label promotional practices related to Bextra, a drug that is not at issue in this Complaint, as well other DOJ investigations involving alleged off-label promotional practices concerning Lyrica, Zyvox, and Geodon, as well as allegations related to certain improper payments and other inducements to healthcare professionals involving those drugs and other additional Subject Drugs. The Settlement also resolved the aforementioned *qui tam* cases.

136. Further, it was announced that the Pfizer had reached agreements with attorneys general in 42 states and the District of Columbia, including Pennsylvania and New Jersey, to settle state civil consumer protection allegations related to its promotional practices regarding Geodon. As a condition of that settlement, Pfizer will pay a total of $33 million to the settling states.

137. The agreement provides a combined federal and state civil settlement of $1billion related to the Subject Drugs. The Company will also pay $1.3billion in criminal penalties related only to Bextra, a drug that is not at issue in this Complaint. As part of the criminal resolution related to Bextra Defendant Pharmacia & Upjohn has agreed to plead guilty to one count of felony misbranding under 21 U.S.C. §§331(a), 33(a) and 352.

138. Aside from the criminal component of the announced settlement, Pfizer agreed to pay another $1 billion to settle civil claims by the government that the Company had violated the False Claims Act, including prohibited off-label use and dosage promotions, and violations of the Federal anti-kickback statute, with respect to 13 different drugs. The terms of the Settlement require Pfizer to make payments to resolve the civil allegations involving past promotional practices with respect to Lyrica in the amount of $50 million. Likewise, Pfizer has agreed to pay $301 million to resolve civil allegations regarding Geodon and $98 million to resolve civil allegations regarding Zyvox. According to the DOJ, this is ***"largest civil fraud settlement in history against a pharmaceutical company."*** Further, as Assistant Attorney General Tony West commented in connection with the announcement of the settlement, "[t]his civil settlement and plea agreement by Pfizer represents yet another example of what penalties will be faced when a pharmaceutical company ***puts profits ahead of patient health***."

139. Pfizer's charged illegal conduct, which spanned almost eight years, between January 1, 2001 and October 31, 2008, involved Company-wide marketing practices and some of Pfizer's most material and important products. Of Pfizer's nine most important pharmaceutical products—those so-called "blockbuster" drugs generating over $1 billion per year in revenue each (representing 60 percent of the Company's total pharmaceutical revenues in 2008)—*seven* (Lipitor, Norvasc, Lyrica, Celebrex, Viagra, Geodon and Zyvox) were included in the $2.3

billion settlement as drugs that were promoted for off-label uses and/or through illegal kickbacks and other improper means.

140. The Civil settlement resolves allegations that Pfizer violated the federal False Claims Act by illegally promoting Geodon, Zyvox and Lyrica, as well as Bextra, a drug not at issue in this Complaint, for uses not approved by the FDA and that were not medically-accepted indications for which the U.S. and state Medicaid programs provided coverage; making and disseminating unsubstantiated and false representations about the safety and efficacy of those drugs; and paying kickbacks to health care providers to induce them to prescribe those drugs. The settlement also resolves allegations that Pfizer was paying kickbacks to health care providers in connection with its marketing of nine other drugs, including the Subject Drugs Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec.

141. The averments of the Information, which Defendant Pharmacia has admitted and fully accepted as part of its guilty plea and conviction, and as part of the Pharmacia Defendants' settlement of the government's investigation, comprise certain core aspects of the fraudulent marketing, promotion and sales scheme and conspiracy alleged by Plaintiff against the Pfizer Defendants, and others, herein, and are incorporated by reference in this Complaint as if fully set forth herein.

142. Pfizer's violations were plainly not isolated incidents, or the work of a small number of "rogue" employees. Rather, the $1 billion payments to settle those charges was the punishment for a deliberate general business strategy designed, implemented and approved at the highest levels of the Company to illegally promote off-label drug use. The settlement agreement summarizes some of this misconduct as follows:

(1) **Bextra**: During the period February 1, 2002, through April 30, 2005, Pfizer:

(a) illegally promoted the sale and use of Bextra for a variety of conditions (including acute pain and various types of surgical pain) and at dosages other than for which its use was approved by the Food and Drug Administration ("FDA") (*i.e.*, "off-label" uses), in violation of the FDCA, 21 U.S.C. § 331, *et seq.,* and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Bextra;

(b) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Bextra, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and

(c) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Bextra. As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Bextra to be submitted to, or caused purchases by, Medicaid and the other Federal Health Care Programs.

(2) **Geodon**: During the period from January 1, 2001, through December 31, 2007, Pfizer:

(a) illegally promoted the sale and use of Geodon for a variety of off-label conditions (including depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism and post-traumatic stress disorder), and for patients (including pediatric and adolescent patients) and dosages that were off-label, in violation of the FDCA, 21 U.S.C. § 331, et seq., and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Geodon;

(b) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Geodon, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and

(c) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Geodon. As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Geodon to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

(3) **Zyvox**: During the period January 1, 2001, through February 28, 2008, Pfizer:

(a) illegally promoted the sale and use of Zyvox for a variety of off-label conditions (including infections caused by methicillin-resistant *Staphylococcus*

aureus ("MRSA") generally, rather than only those types of MRSA infections for which Zyvox was FDA-approved), in violation of the FDCA, 21 U.S.C. § 331, *et seq.,* and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Zyvox;

(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zyvox (including that Zyvox was superior to vancomycin, its primary competitor drug for these indications); and

(c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zyvox, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Zyvox to be submitted to, or caused purchases by, Medicaid, Medicare and other Federal Health Care Programs.

(4) **Lyrica**: During the period September 1, 2005, through October 31, 2008, Pfizer:

(a) illegally promoted the sale and use of Lyrica for a variety of off-label conditions (including chronic pain, neuropathic pain, perioperative pain, and migraine), in violation of the FDCA, 21 U.S.C. § 331, *et seq.,* and which were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6) for which the United States and state Medicaid programs provided coverage for Lyrica;

(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Lyrica, including claims that is was superior to Neurontin and its generic equivalent, gabapentin; and

(c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Lyrica, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b). As a result of the foregoing conduct, Pfizer knowingly caused false or fraudulent claims for Lyrica to be submitted to, or caused purchases by, Medicaid, Medicare and other Federal Health Care Programs.

(5)**Kickbacks**: From January 2001, through December 2004, Pfizer paid illegal remuneration for speaker programs, mentorships, preceptorships, journal clubs, and gifts (including entertainment, cash, travel and meals) to health care professionals to induce them to promote and prescribe the drugs Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, Pfizer caused false claims to be submitted to Medicaid and TRICARE.

143. Also as part of the settlement to resolve the federal government's charges and the civil liabilities, Defendant Pfizer has entered into a comprehensive five-year Corporate Integrity Agreement ("CIA") with the HHS-OIG. The CIA requires enhanced accountability, increased transparency and wide-ranging monitoring activities conducted by both internal and independent external reviewers. The CIA also requires that an Audit Committee of Pfizer's Board of Directors annually review the company's compliance program and certify as to its effectiveness; and also that senior executives annually certify about compliance with the requirement that Pfizer notify doctors about the global settlement and establish a mechanism doctors can use to report questionable conduct by a Pfizer representative and that the company post on its web site information about payments to doctors, such as honoria, travel or lodging.

144. The Plaintiffs, Ms. Zafarana and Mr. Dumville and the Class have filed this action because the agreement to resolve the federal government's investigation against the Pfizer Defendants will not compensate the Plaintiffs and the Class for all of the damages they have suffered and all of the damages to which they are entitled under all applicable laws.

145. Indeed, the civil Qui Tam cases pending in the Districts of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky, which upon information and belief seek broad relief for the federal government's losses incurred as to the Subject Drugs as a result of Defendants' fraudulent scheme and conspiracy will not compensate Plaintiff and the Class for their injury and damages.

a) Pfizer's New Obligations Under the 2009 CIA

146. As mentioned above, in addition to paying the largest criminal fine and the largest civil fraud settlement in history, the government imposed on Pfizer's Board yet another Corporate Integrity Agreement (the "2009 CIA"). The 2009 CIA supersedes the 2004 CIA and

includes additional, enhanced compliance requirements that directly reflect the government's loss of faith in the ability of Pfizer's senior management and the Board to ensure Pfizer's compliance with the FDCA, the Federal anti-kickback statute and other healthcare regulations. In large measure, the 2009 CIA reflects a government takeover of monitoring and ensuring corporate governance at Pfizer because of the repeated and knowing refusal of senior management and the Board to do so.

147. *First*, the 2009 CIA imposes new obligations on the Audit Committee, requiring the Audit Committee to meet quarterly to review and oversee the Company's compliance activities and evaluate their effectiveness. Moreover, upon each quarterly review, the Audit Committee must adopt a resolution summarizing its inquiry into and oversight of Pfizer's compliance with federal health program requirements, FDA regulations and the Company's obligations under the CIA. The resolution—which must be signed by each individual member of the Audit Committee—must verify that Pfizer's compliance program has been effective to "meet Federal health care program requirements, FDA requirements, and the obligations of the CIA." If an Audit Committee member is unable to provide such an affirmation, the Audit Committee must include a written explanation of the reasons "why it is unable to provide the conclusion and the steps it is taking to assure implementation by Pfizer of an effective Compliance Program at Pfizer."

148. *Second*, the 2009 CIA mandates similar compliance measures for management, requiring that the presidents and finance directors of each business unit involved in pharmaceutical sales complete a certification affirming that they have taken appropriate steps to ensure compliance, that the relevant business unit's leadership team has not directly or indirectly encouraged policy violation, and that controls are operating effectively. Similar to the

verifications required of the Audit Committee members, the management certifications must also affirm that the certifying individual has reviewed 1) internal reports addressing promotional quality assessments; 2) reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses; 3) sales compensation exclusion criteria; and 4) corporate compliance group statistics. In addition, the certifying executive must verify that no violation of law, regulation, Pfizer policy or the CIA has occurred, or if an issue has been identified, affirm that the potential violations have been referred to the Corporate Compliance Group or a member of the Pfizer legal division.

149. *Third*, the 2009 CIA requires the Board to review compliance measures on a more frequent basis, requiring that the Chief Compliance Officer submit reports to the Board's Audit Committee on at least a quarterly basis. Further, the Chief Compliance Officer—who can no longer be the same individual who acts as a general counsel for the Company—cannot be subordinate to the General Counsel or the CEO, but must be a member of senior management who reports directly to the Chief Executive Officer. This significant change will require Douglas M. Lankler, who currently serves as Pfizer's Chief Compliance Officer and who signed the 2002 and 2004 CIAs, be replaced, and represents a significant departure from the practice under the 2004 CIA, under which Kindler acted as both Pfizer's General Counsel and its Chief Compliance Officer.

D. DEFENDANTS' CONSPIRACY TO INDUCE PRESCRIPTIONS OF SUBJECT DRUGS BY OFFERING IMPROPER REMUNERATION TO PHYSICIANS

150. During the applicable time period, the Pfizer Defendants engaged in a scheme and conspiracy with healthcare providers and others, which were intended to induce, and did induce, providers to prescribe Subject Drugs to patients, despite the availability of less expensive, approved, alternative courses of treatment. As a direct result of Pfizer's scheme and

conspiracy, as Plaintiff, who was approximately six years of age at the time, was prescribed Geodon, an adult antipsychotic with serious adverse effects. Geodon was ineffective in treating Plaintiff's condition and much more expensive than a more effective and less costly alternative. Further, as a direct result of Pfizer's scheme and conspiracy, Plaintiff, M.A.C., was prescribed an unsafe and ineffective treatment for a period of approximately three years, thus depriving him an effective treatment for his condition. Pfizer's scheme and conspiracy, as detailed herein, directly resulted in M.A.C., being prescribed Geodon off-label, instead of him undergoing treatment with inexpensive over-the-counter medications such as Melatonin, and other treatments which are less costly and have fewer harmful side effects than Geodon.

151. Following are examples of practices used by the Pfizer Defendants which were intended to encourage, and did encourage, healthcare providers to prescribe Subject Drugs over less expensive, approved, alternative courses of treatment. On information and belief, Plaintiff's healthcare provider was influenced by, and prescribed Geodon to Plaintiff and the Class Members as a result of, one or more of these practices.

i. Phony Speaker Fees paid for by "Honorariums"

152. Upon information and belief, the Pfizer Defendants' sales representatives paid "honorarium" fees to physicians, ostensibly as compensation to physicians for agreeing to speak at a formal function, such as a dinner. However, in most instances, the lectures were promotional in nature for off-label uses of the Subject Drugs. Upon information and belief, honorariums were sometimes provided as cash, or as reimbursement for travel, or for some other improper cost.

ii. Phony Preceptorships

153. Upon information and belief, the Pfizer Defendants' "preceptorship" programs were ostensibly a teaching session in which a sales representative's physician (in his or her area) would agree to teach the sales representatives certain technical aspects of his or her practice in exchange for a sum of money. In numerous ways, these "preceptorships" lacked the characteristics of legitimate preceptorships and often were used as kickbacks by sales representatives as a means of improperly providing cash to the physicians.

iii. Free Samples

154. Upon information and belief, the Pfizer Defendants provided free samples of their drugs, *inter alia* Norvasc, Lipitor, Viagra, Zyrtec, Zithromax, Zoloft, Celebrex, etc. As detailed in Blair Collins' Whistleblower complaint, Pfizer directed their sales forces to "flood offices" with samples of the subject drugs to the maximum capacity. That meant not only having the office's sample closets to be filled to the capacity, but the sales representatives would also ask the nurses and medical assistants which drawers they were not using and subsequently fill those drawers with samples. In addition, they would remove paper towels and ancillary items from cabinets over the counters and fill those with samples, so that there were samples in every vacant drawer, every partially used cabinet, and on every counter in each medical office.[27]

155. The nurses, medical assistants and physicians are not allowed to throw samples away. Rather, FDA regulations require that if the samples expire they must be returned to the representatives (and in the case of Pfizer returned to Brooklyn for destruction). Most of the

[27] Complaint at ¶231, *United States ex rel. Blair Collins, et al., v. Pfizer, Inc.* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

medical staff and nurses did not want to offend the Pfizer representatives by returning the samples (i.e. they didn't want the nice lunches, dinners, breakfasts, and socials to slow down).[28]

156. The result was that most patients who needed a blood pressure lowering agent got Norvasc, even if they got another agent too. Most patients who needed lower cholesterol got Lipitor, most who complained of depression, soft erections or severe pain, got Zoloft, Viagra and Celebrex samples put aside for them before they even arrived at the office for their appointment. Samples were replaced within one to two days, as there were never more than three days that went by that a doctor did not see a Lipitor, Norvasc, Viagra, Zithromax, Zyrtec, Zoloft or Celebrex representative.[29]

iv. Distribution of Misleading and False Information Regarding the Safety and Efficacy of Pfizer's Drugs

157. Upon information and belief, the Pfizer Defendants distributed misleading literature and provided false information regarding the safety and efficacy of the Subject Drugs. Specifically, as discussed below, Pfizer distributed misleading literature to providers regarding head to head comparisons of their drugs and a competitor product that falsely demonstrated that Pfizer's product was in some way superior to its competitor. Further, Pfizer provided misleading and false information regarding the safety and efficacy of its drugs throughout various speaking engagements, telephone calls and conferences with providers and TPPs and by and through their sales representatives who provided false information directly to physicians in the course of their traditional detailing. Further, Pfizer funded scientific studies that misrepresented the evidence supporting the safety of the Subject Drugs. Pfizer did all of this with the intent to mislead and sway a given provider's independent medical judgment to prescribe a Pfizer product. Upon

[28] *Id.* at ¶232
[29] Complaint at ¶¶233-34, *United States ex rel. Blair Collins, et al., v. Pfizer, Inc.* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

information and belief, as a direct result of the Pfizer's misleading literature and false representations, Plaintiff, M.C.'s physician prescribed him Geodon.

v. Other Inducements

158. Upon information and belief, the Pfizer Defendants have also provided and/or arranged for many other financial and other forms of inducements to stimulate sales of the Subject Drugs at the expense of Plaintiff and the Class. Such inducements included, but were not limited to, the provision of gifts in the form of cash, entertainment, travel and meals. Further, the Pfizer Defendants distributed misleading literature regarding the safety and efficacy of the Subject Drugs, promoted CME and other purported educational lectures that were in fact promotional in nature for off-label uses of the Subject Drugs, funded scientific studies that misrepresented the evidence supporting the safety of the Subject Drugs, funded roundtable discussions, promotional advertisement, journal supplements and Pfizer sponsorship of physician meetings and provided Pfizer-prepared and funded promotional materials to be used by physicians that were paid to promote the Subject Drugs.

V. PFIZER'S IMPROPER AND ILLEGAL MARKETING AND PROMOTION OF GEODON

A. BACKGROUND ON PFIZER'S UNLAWFUL PROMOTION OF GEODON

159. Geodon's FDA approval in 2001 placed Pfizer at an initial disadvantage in the market for schizophrenia drugs since it was a fourth atypical antipsychotic drug on the market. Disappointing revenues during 2001 and 2002 led Pfizer to increase their promotional efforts of Geodon to reach an annual sales goal of $1 billion by 2004.

160. At Pfizer's National Sales Meeting held in November, 2002, Pfizer's sales managers, Vice Presidents from corporate sales and Regional Medical Research Specialists ("RMRSs") were encouraged to promote Geodon for unapproved uses including: borderline

personality disorder, refractory mood disorders (depression, obsessive compulsive disorder, post traumatic stress disorder), dementia in the elderly, bipolar mania, bipolar maintenance and, pediatric/adolescent conduct disorders. The presentation at the National Sales Meeting did not include any information regarding Geodon's significant side effects; the only goal was to "increase sales wherever possible."[30]

161. For example, Pfizer's District Manager in Chicago, John Hutt executed Pfizer corporate Geodon strategy by training his sales representatives on off-label promotion. Mr. Hutt, directed sales representative Bob Burrell to conduct an off-label presentation for other sales representatives to demonstrate the promotion of Geodon for depression, mood disorders, post traumatic stress disorder, bipolar disorder and ***adolescent use.***[31]

B. PFIZER'S UNLAWFUL PROMOTION OF GEODON TO DOCTORS TREATING PATIENTS WHO WOULD NOT USE IT FOR ANY APPROVED CONDITION

162. As set forth in more detail by whistleblowers Mark Westlock and Stefan Kruszewski, one of Pfizer's off-label marketing methods focused on solicitation of doctors who did not treat patients with conditions related to the subject drug's FDA-approved uses. For example, Mark Westlock and Stefan Kruszewski, former Pfizer sales representatives explained in their whistleblower complaints that it was common for sales representatives to market Geodon to doctors who do not treat schizophrenia or bipolar patients (such as primary care physicians) or to psychiatrists who do not treat patients who can be treated using Geodon on-label (child and adolescent psychiatrists).[32] Moreover, despite the fact that Geodon has a block box warning

[30] Complaint¶¶153-58, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et a*l., Civ. No. 08-CA-11318 DPW, (D. Mass. Aug. 22, 2008).
[31] Complaint ¶158, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et a*l., Civ. No. 08-CA-11318 DPW, (D. Mass. Aug. 22, 2008) (emphasis added).
[32] Complaint ¶¶214-15, *United States ex rel. Mark R. Westlock, et al. v. Pfizer, Inc., et a*l., Civ. No. 08-CA-11318 DPW, (D. Mass. Aug. 22, 2008).

against using it for treating elderly patients with dementia, Pfizer regularly promoted Geodon to doctors treating this population in order to boost Geodon sales.[33]

163. As part of their promotional campaign, Pfizer had a large number of ***child psychiatrists routinely paid*** substantial honorariums to give purportedly "educational" lectures about Geodon, although these lecture were strictly promotional. By hiring pediatric psychiatrists to lecture on Geodon, Pfizer was seeking to expand Geodon's off-label market share among pediatrics. Doctors under the influence of pharmaceutical company propaganda and fanatical "incentives" to prescribe these drugs are putting children's lives at risk by prescribing these highly toxic drugs. Dr. Ronald Brown, who headed an American Psychological Association committee that evaluated the issue, put it succinctly: "the bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness."[34]

164. In his complaint, Mark Westlock explained that solicitation of doctors who did not treat patients with conditions related to Geodon's FDA-approved uses was common. Specifically, Mr. Westlock (as well as other Pfizer sales representatives) had numerous child and adolescent psychiatrists included in his call-cycle to whom he was expected to sell Geodon. This was common for all other sales representatives.[35]

165. During their Geodon detailing of Dr. Kruszewski, Pfizer representatives encouraged him to prescribe Geodon for unapproved uses such as agitation, delirium, dementia, use in children and adolescents, depression, psychotic states unrelated to schizophrenia and schizoaffective disorder. Specifically, without solicitation by Dr. Kruszewski, Pfizer representatives encouraged him to use Geodon for treatment in children and adolescents by

[33] *Id.* at ¶206; Complaint ¶73, *United States ex rel. Stefan Kruszewski, et al. v. Pfizer, Inc., et al.,* Civ. No. 07-04106 BWK (E.D.Pa. Aug. 21, 2009).
[34] Complaint at ¶81, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[35] *Id.* at ¶214-15.

offering to set up a one-on-one dinner lecture between Kruszewski and an established Pfizer-sponsored child and adolescent psychiatrist.[36]

166. Geodon prescriptions written in children in the United States have been growing tremendously. A recent report by the University of South Florida found the most common diagnosis for antipsychotic treatment for children in Florida's Medicaid program between July and December 2005 was for ADHD. Fifty-four percent involved children five years of age and younger, while forty-nine percent involved kids between the ages of six and twelve. According to the study, the Florida Medicaid bill for these drugs jumped from $9 million in 1999 to nearly $30 million in 2006. Florida Medicaid records show the number of children-some just months old-who were prescribed SGAs went from 9, 364 in 1999 to 18, 137 in 2006.[37]

i. Using Quota and Credit Programs to induce Sales to doctors and facilities who did not use Geodon.

167. Furthermore, Pfizer's national Geodon sales strategy included quota and credit programs that both penalized and incentivized the sales force to sell to doctors who could not treat their patients using Geodon on-label. The quota and credit programs were instituted immediately upon Geodon's approval in 2001, and applied to sales representatives, District managers, Regional managers and Vice Presidents.[38]

168. Pfizer's quota system required Geodon sales representatives to detail any physician on their call list (regardless of specialty) and awarded them with bonuses based on sales of Geodon. For instance, Geodon sales representatives that exceeded quota of, for example, 105% would be paid additional bonus dollars and additional chances of winning award trips. The prescribers Pfizer included in its quota and credit programs were doctors that would not normally

[36] *Id.* at ¶¶71, 90.
[37] Complaint at ¶83-84, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[38] *Id.* at ¶ 217.

treat patients with Geodon's approved indications such as child psychiatrists, primary care physicians and geriatric physicians (including calling directly on nursing homes).[39]

C. PFIZER'S UNSUBSTANTIATED SUPERIORITY CLAIMS AND MISREPRESENTATIONS REGARDING GEODON'S SIDE EFFECTS

169. Pfizer has also knowingly and deliberately falsely promoted Geodon by the use of unsubstantiated comparative claims, comparing Geodon with competing drugs on the market such as Seroquel, Ambilify, Zyprexa and Resperdal.

170. Since FDA-approval, Pfizer has falsely marketed and promoted Geodon as a safer alternative to other atypical antipsychotics. Despite the evidence to the contrary, Pfizer-sponsored advertisements have misleadingly stated that Geodon has minimal ability to cause neurological side-effects. However, it is now well-established in peer reviewed medical literature that the significant side effects associated with Geodon include, extrapyramidal symptoms ("EPS") including akathisia, tremor, and hypertonic/dystonic reactions.[40]

171. Specifically, Dr. Kruszewski, a widely recognized, Board Certified scientists and psychiatrists was not only an eyewitness to Geodon off-label promotional marketing by Pfizer representatives, but also reviewed promotional materials from Pfizer, including advertisements, lecture slides and educational materials. After careful review of Pfizer's promotional materials, Dr. Kruszewski found the scientific content that underscored the data put forth by Pfizer's promotional materials inconsistent, unbalanced and misleading.[41]

172. On September 19, 2005, the National Institute of Mental Health published the results of the most comprehensive comparative study ever conducted: Clinical Antipsychotic

[39] Complaint at ¶¶218-20, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[40] Complaint ¶33, *United States ex rel. Stefan Kruszewski, et al. v. Pfizer, Inc., et al.,* Civ. No. 07-04106 BWK (E.D.Pa. Aug. 21, 2009).
[41] *Id.* at ¶31.

Trials of Intervention Effectiveness ("CATIE" study). The results that were published in the New England Journal of Medicine, found that SGAs like Geodon were no more effective and no safer in the treatment of schizophrenia than older, cheaper drug that has been largely discontinued. The newer antipsychotics were praised for not causing involuntary muscle movements that the older antipsychotics have been known to cause. However, the lead author of the CATIE study, Jeffrey Lieberman noted that earlier comparisons with older drugs, largely funded by drug manufacturers, had mostly used a highly potent drug called Haldol, whereas the CATIE study did not find the same degree of movement problems with a less potent drug.[42]

173. Contrary to Pfizer's promotional materials and methods, Geodon is similar to resperidone, quetiapine and olanzapine in that it also can induce serious neurological side effects, increase blood lipids, induce weight gain, induce hypertension, and increase risk of edema, rash and infection.[43]

D. PFIZER PROMOTED GEODON FOR UNAPPROVED USES AS A MAINTENANCE MEDICATION IN THE LONG TERM TREATMENT OF BIPOLAR DISEASE.

174. Even though the FDA had only approved Geodon for short-term use for 21-day increments in bipolar patients prevalent in emergency settings not primary care settings, Pfizer directed its sales representatives to use materials that marketed Geodon as a maintenance drug for long-term treatment of bipolar patients.[44]

175. In June 2007, the Pfizer Geodon Disease Management Team (in charge of preparation of marketing materials for Geodon), sent a DVD to all Powers District Managers to share "best practices" from the top three performing sales districts. In the video was Kevin Kirk,

[42] Complaint at ¶135-36, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[43] Complaint at ¶73, *United States ex rel. Stefan Kruszewski, et al. v. Pfizer, Inc., et al.,* Civ. No. 07-04106 BWK (E.D.Pa. Aug. 21, 2009).
[44] Complaint at ¶225, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).

a Pfizer sales representative from West Virginia. In his presentation, Kirk stated, "that Geodon works for 55 weeks in bipolar disorder patients." However, there was no clinical data to support this, nor had Geodon ever been approved as a maintenance drug treatment of bipolar disorder.[45]

E. PFIZER USED REGIONAL MEDICAL RESEARCH SPECIALISTS ("RMRSs") AND "THOUGHT LEADERS" TO PROMOTE GEODON FOR UNAPPROVED USES.

176. Another Pfizer strategy to promote Geodon® for non-approved uses is the use of Pfizer Regional Medical & Research Specialists ("RMRSs") as an end-around to sales representatives' duty to lawfully promote Geodon®. Pfizer's use of RMRSs in this manner was a way for Pfizer to make the unlawful promotional activities for Geodon® appear lawful. [46]

177. Pfizer employs RMRSs to engage in non-promotional medical activities, such as answering questions from doctors about Pfizer products and recruit/pre-screen medical clinics that have the capacity to support approved clinical studies. Although RMRSs are not to be engaged in product promotion, nonetheless RMRSs regularly accompany Pfizer sales representatives on sales calls, including on Geodon® sales calls.[47]

178. Despite Pfizer's stated policy that investigational or unapproved uses could not be presented by a Pfizer-sponsored speaker, its sales force regularly used contracted speakers to make presentations which included unsolicited materials concerning investigational and/or unapproved uses of Geodon. With Pfizer's knowledge and approval, Pfizer speakers touted unapproved uses for Geodon, both verbally and in written materials, such as power point slides. Written materials that included unapproved uses were disseminated to Pfizer's sales force.[48]

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[45] *Id.* at ¶226.
[46] Complaint at ¶183, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[47] Complaint at ¶184, *United States ex rel., Mark R. Westlock, et al., v. Pfizer, Inc., et al.,* Civ. No. 08-CA-11318 DPW (D. Mass. Aug. 22, 2008).
[48] *Id.* at ¶¶159-63.

VI. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF ZYVOX

179. As detailed in Ronald Rainero's whistleblower complaint, Pfizer had unlawfully promoted Zyvox using substantially similar marketing tactics described above. Pfizer has more than 360 sales representatives promoting Zyvox to physicians and pharmacists in the US.[49]

A. PFIZER'S FRAUDULENT PROMOTION OF ZYVOX TO DOCTORS TREATING PATIENTS WHO WOULD NOT USE IT FOR ANY APPROVED INDICATION

180. Zyvox's indications are commonly known as pneumonia and skin infections. Despite these indications, Pfizer has provided financial incentives to its sales representatives to promote Zyvox for variety of off-label uses to nephrologists in kidney dialysis centers, and oncologists in chemotherapy/cancer centers, since the patients at these centers are at high risk for developing catheter related bloodstream infection and concomitant bloodstream infections. Pfizer had also directed its sales representatives to promote Zyvox to vascular surgeons, who generally treat catheter related skin infections and concomitant blood stream infections, even though vascular surgeons have no reason to treat pneumonia and skin infections. However, Pfizer's promotion of Zyvox for such treatment is very profitable because catheter related skin infections require 14 to 21 days of antibiotic therapy compared to the maximum of seven days for treatment of pneumonia.[50]

181. Pfizer has also fraudulently promoted Zyvox for post surgical site infections to surgeons at community hospitals who typically do not treat pneumonia and skin infections.

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[49] Complaint at ¶36, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).
[50] Complaint at ¶¶39, 42, 43*United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).

B. PFIZER'S PROMOTION OF ZYVOX AS CLINICALLY SUPERIOR TO VANCOMYCIN

182. In Zyvox's prescribing information, Zyvox achieved cure rates of 61% for nosocomial pneumonia caused by *Staphylococcus aureus* (Vancomycin cure rates of 61%), 59% nosocomial pneumonia cased by MRSA (compared to 70% for Vancomycin) and 100% nosocomial pneumonia caused by *Steptococcus pneumonia (*compared to 90% for vancomycin).[51] Moreover, Pfizer has widely promoted the results of a study authored by Richard Wunderlink which concluded that Zyvox was superior to vancomycin in the treatment of MRSA nosocomial pneumonia.(The promotion of this study was one of the subjects of the FDA warning letter issued in July 2005).[52]

183. However, in June 2004, several FDA scientists published an article in the same journal concluding that the Wunderlink study was flawed because it was based on retrospective subgroup that was not randomized. The article stated that "the results of the Wunderlink study support the conclusion that the efficacy of linezoid and vancomycin are similar in patients with NP (nosocomial pneumonia) … Trials of MRSA NP may have logistical difficulties, but this does not justify accepting conclusions or basing future guidelines for patient care on *less than optimal data."*[53]

184. Despite the data to the contrary, Pfizer continued to mislead the public, healthcare providers and the FDA that Zyvox was superior to vancomycin in nosocomial pneumonia.

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[51] *Id.* at ¶¶68,69

[52] Complaint at ¶70, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).

[53] Complaint at ¶71, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008)..

C. PFIZER'S PROMOTION OF ZYVOX FOR STEP-DOWN THERAPY

185. Pfizer also promotes Zyvox for "step-down therapy." "Step down therapy" is the phrase used to describe the transition from intravenous antibiotics to oral antibiotics of the same brand. Zyvox is one of several antibiotics that are effective against MRSA that come in both intravenous and oral formulations.

186. John Weiglet MD., DVM, a professor at the Medical College of Wisconsin and a Zyvox speaker, summarized Pfizer's marketing message by stating that "the ability to treat MRSRA with oral ZYVOX may reduce patients' risk for additional infections and allow them to potentially recover in the comfort of their own home without the need for an IV line-which is especially important in instances where the patient would not otherwise be hospitalized." Dr. Weiglet also stated that "[p]revious studies have demonstrated cost savings associated with oral Zyvox due to shorter hospital stays." However, this belies the fact that many patients simply cannot afford oral Zyvox upon discharge from hospital. [54]

187. Pfizer's promotion of "step down therapy" is flawed and **endangers public health** because the oral form of Zyvox is very expensive and many times insurance companies do not cover it. As a result, when patients attempt to fill their prescriptions for oral Zyvox they find out that either they can't afford it or the insurance won't cover it, thus they often fail to fill their oral Zyvox prescription as the full course of Zyvox therapy is not finished. When a patient doesn't complete the full course of therapy, the potential for resistance to Zyvox emerges. [55]

188. On January 19, 2007, the State of New York Department of Health issued a letter to all Zyvox prescribers concerning the public health risks posed by overuse and misutilization of

[54] *Id.* at ¶¶120-22, (Oral Zyvox tablets costs approximately $148 a day. The length of Zyvox oral therapy can be anywhere from 3 days to 21 days. For a patient not covered by insurance, this can mean an out of pocket expense anywhere from $444 to $3,108).
[55] Complaint at ¶124, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).

Zyvox. The letter informed doctors that "***due to public health concerns and the potential for overuse and misutilization, NYS Medicaid requires that prescribes obtain prior authorization before prescribing Zyvox." "This requirement reinforces the prescribers should carefully consider alternatives before initiating Zyvox therapy in the outpatient setting."*** Furthermore, the letter stated "… overuse of this agent (Zyvox) will accelerate the development of resistance and limit its overall effectiveness." Thus the Department of health letter concluded that "Zyvox should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Cultures should be done and susceptibility proven prior to prescribing the agent. ***Zyvox should be reserved for use against Vancomycin Resistant Enteroccocci ("VRE")***[56].

189. The widespread off label promotion of Zyvox by Pfizer for non-FDA approved purposes poses a grave public risk because it increases the risk that linezolid (Zyvox) resistance eterococci will develop and also increases the risk that more Zyvox resistant bacterial strains will develop.

VII. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF LYRICA

A. BACKGROUND OF LYRICA SCHEME

190. Pfizer knew from its Neurontin® ("Neurontin") experience that promoting a drug product for as many indications as possible would result in dramatically increased sales of its follow-on drug product, Lyrica. In the case of Neurontin, approximately 70% to 90% of its sales were reportedly for off-label use, and had resulted in annual sales of nearly $3 billion per year at the time the first generic came on the market in 2004. Upon information and belief, Pfizer

[56] Complaint at ¶¶125-28, *United States et al. ex rel. Ronald Rainero v. Pfizer, Inc.*, Civ. No. 07-CA-11728 DPW (D. Mass. June 19, 2008).

intended to replicate its Neurontin success with Lyrica, Neurontin's follow-on branded drug product in the anti-epileptic drug ("AED") class.

191. Replacing the revenue lost by competition to Neurontin was critical for Pfizer once Neurontin lost its patient protection, and generic gabapentin started flooding the market beginning in 2004. Thus, Pfizer developed Lyrica. To replace the revenue lost by Neurontin.

192. On August 18, 2004, generic manufacturer Ivax announced it had launched "at risk" its generic version of Pfizer's Neurontin, gabapentin, in 100 mg and 400 mg strengths. Pfizer had originally intended to launch Lyrica prior to generic competition for gabapentin. However, according to reports in the "Pink sheet" dated August 23, 2004, the Lyrica New Drug Application ("NDA") filing had been delayed at least three years by a number of issues, including carcinogenicity and toxicological data, FDA's determination that Lyrica would be a Schedule V controlled drug (due to its potential for euphoric effects, abuse, and dependence), and whether the FDA would approve Lyrica generalized anxiety disorder (*i.e.*, "GAD"). The FDA gave Pfizer a not-approvable for GAD in 2004.

193. On December 31, 2004, the FDA approved Lyrica for treating two conditions" (1) Diabetic Peripheral Neuropathy ("DPN" – diabetic nerve pain); and (2) Post Herpetic Neuralgia ("PHN" – pain associated with shingles). According to the Pfizer Lyrica website, these two conditions were to be treated with Lyrica "just to treat the burning, stabbing, shooting symptoms of nerve pain caused by diabetes or shingles." On June 13, 2005, Lyrica was approved by the FDA as an adjunct therapy to treat partial onset seizures in adults with epilepsy.

194. Not only did Pfizer face the challenge of getting physicians to prescribe Lyrica instead of the gabapentin, which began flooding the market, it faced a new challenge with the introduction by competitors of products in the category, particularly Eli Lilly's drug Cymbalta®

("Cymbalta") which was approved by the FDA for major depressive disorder and diabetic peripheral neuropathy on August 3, 2004, and UCB's drug Keppra® ("Keppra"), which is FDA-approved as an adjunctive treatment for partial onset seizures in adults and children four (4) years of age, myoclonic seizures in adults, and primary generalized tonic-clonic seizures in adults and children six (6) years of age and older with idiopathic generalized epilepsy. There were also reports that Lilly was pursuing fibromyalgia and generalized anxiety disorder indications for Cymbalta as well. *See* "Pink Sheet," December 20, 2004, p. 19.

195. Armed with FDA approval, Pfizer placed Lyrica on the market. However, given the limited indications approved by the FDA and intense competition, Pfizer faced only limited market potential for Lyrica's approved uses. Nonetheless, the company made the calculated business decision to replicate Neurontin's success by the illegal off-label marketing and misbranding of Lyrica. Thus, Pfizer implemented its illegal Lyrica's promotional programs with the formal launch of the drug in September 2005.

196. As described below, Pfizer began its off-label promotion and misbranding of Lyrica immediately after it began selling the drug in August, 2005, and upon information and belief continues to illegally promote Lyrica, thereby intentionally and knowingly violating the terms of the Neurontin CIA. But for Pfizer's illegal promotion, these off-label and misbranded prescriptions for Lyrica would not have been written. According to realtor Robert Liter, the sales representatives were specifically instructed to promote Lyrica for the following off-label uses: pain control, bipolar disorder, back pain, generalized anxiety disorder, post surgical pain, social anxiety disorder, migraine headache, multiple sclerosis, acute dental pain, pain due to spinal cord injury, thalmatic pain syndrome, and many more diseases and conditions. The sales representatives were further provided unapproved studies comparing the efficacy of Lyrica with

Neurontin (gabapentin), Cymbalta, Keppra and several other drugs and encouraged sales representatives to utilize those studies to promote the sale of Lyrica

197. One of Pfizer's goals which Pfizer communicated to several Relators and the rest of the Pfizer sales force, was to convert every gabapentin prescription to a Lyrica prescription, including those Neurontin prescriptions that were written for off-label uses as a result of Pfizer's prior illegal promotion of Neurontin. To accomplish the Lyrica for gabapentin conversion goal, Pfizer deliberately promoted Lyrica as being more effective than gabapentin, knowing no head-to-head efficacy studies comparing the two drugs were available. Beginning shortly after the launch in 2005, Pfizer disseminated false and misleading promotional literature to its sales force and the medical community, including marketing materials, comparing Lyrica to gabapentin, and thereby misbranded Lyrica in violation of the FD&C Act.

198. Similarly, Pfizer deliberately promoted Lyrica as being more effective in reducing seizures than Keppra although no head-to-head pharmacological studies comparing the drugs had been conducted at the time. What makes this promotion even more egregious is that Keppra is FDA-approved as adjunctive therapy to treat several different forms of epilepsy in adults as well as children (as explained above), while Lyrica is only approved as adjunctive treatment for one form of epilepsy in adults.

199. Pfizer instructed representatives they were not to mention, or in any way highlight or draw attention to the fact, that the Lyrica study on which Pfizer relied to make its unsubstantiated and deliberately misleading head-to-head comparisons, was a study for partial onset seizures in adults, the only epileptic condition for which Lyrica treated the same types of epilepsy as Keppra. Pfizer representatives were trained to, and did, use "Pfizer math" to

intentionally create the false impression that there had been head-to-head comparisons between Keppra and Lyrica showing Lyrica's superiority when there were no such studies.

200. Moreover, Pfizer's illegal promotion also included off-label promotion of Lyrica through the use of various programs. These programs included (1) targeting physicians who did not treat the FDA-approved uses, such as psychiatrists and orthopedists; (2) explicit and implicit directions to Pfizer's sales representatives to market Lyrica off-label; (3) providing free Lyrica vouchers to induce physicians to prescribe Lyrica off-label; and (4) payments to speakers and Pfizer medical specialists to promote Lyrica off-label.

201. In addition to directing sales representatives to promote Lyrica for the treatment of any kind of pain, some of the conditions which Pfizer has promoted Lyrica for off-label use include migraine headaches and spinal pain.

202. To bolster its illegal promotion of Lyrica to physicians, Pfizer paid monies to its identified "thought leaders"—*i.e.*, heavy Neurontin prescribers who were also Pfizer speakers in order to induce them to recommend Lyrica for addition to formularies, including Medicaid formularies.

203. Pfizer's illegal promotional campaign included the following:

a. Directing sales representatives to discuss with physicians Lyrica's efficacy relative to gabapentin and other drugs in the absence of pharmacokinetic, peer-reviewed studies supporting such claims;

b. Using promotional materials provided to all Pfizer sales representatives with improper and unsupported side-by-side claims of the efficacy of Lyrica in comparison with gabapentin in the absence of pharmacokinetic, peer-reviewed studies supporting such claims;

c. Using Pfizer-sponsored studies which raised additional non-FDA approved indications ("secondary endpoints"), as additional uses for Lyrica, including as an aid for sleep disorders;

d. Directing sales representatives to contact orthopedists, reconstructive surgeons, psychiatrists, and numerous other physicians who do not treat patients with any of the conditions for which Lyrica is approved, and whose only reason for being contacted was that they had been off-label prescribers of Neurontin;

e. Using a sales pitch which "required" sales representatives to tout Lyrica for treatment of "any kind of pain" despite it only being FDA-approved for neuropathic pain associated with PHN and DPN, and as adjunct therapy for adult onset epilepsy;

f. Using relationships with "thought leaders" (many of who had been heavy off-label prescribers of Neurontin) who were recipients of significant speaker fees, research grants, and other Pfizer monies to influence their recommendations for the addition of Lyrica to formularies, including Medicaid formularies;

g. Providing "Do Not Detail" off-label materials to marketing representatives, which Pfizer intended would in fact be used in the off-label promotion of Lyrica, including materials touting the use of Lyrica for the treatment of fibromyalgia;

h. Directing off-label sales promotion to psychiatrists not be logged into the Pfizer sales databases so they could not be tracked as off-label sales promotions;

i. Using "insell" off-label marketing pitches to hospital physicians, including psychiatrists for treatment of pain, which cannot be tracked as being off-label in the Pfizer databases; and

j. Paying speakers and "medical specialists' to promote Lyrica off-label.

B. MAKING COMPARATIVE EFFICACY CLAIMS OF LYRICA TO KEPPRA

204. Notwithstanding that Lyrica had been FDA-approved as adjunctive therapy for the treatment of partial onset of seizures in adults, shortly after the Lyrica launch, Pfizer realized that neurologists who were the most likely to be prescribing Lyrica on-label were rarely prescribing the drug and instead were using a competing manufacturer's product, Keppra. In fact, for the treatment of seizures, Keppra was the drug of choice among many treating neurologists. With this in mind, Pfizer undertook a concerted effort through the use of POA

meetings and conference calls to develop specific strategies aimed at unseating Keppra as the leading treatment for seizures and increasing Lyrica's market share in this area.

205. In furtherance of this strategy, for example, on May 9, 2006, at the Technology Park Hilton in Denver, Colorado, Pfizer's senior sales management again directed the Therapeutic Specialty Representatives ("TSRs"), that they were to undertake a "Compare and Win" detail, comparing the purported efficacy of Keppra to Lyrica. To do this, Pfizer instructed representatives they were to use seizure reduction data from two separate studies (one for Lyrica and one for Keppra) to illustrate Lyrica's superiority. According to the directives given, even though there had not been a head-to-head trial, sales representatives were to create the impression for doctors that there had been such a head-to-head trial.

206. According to senior Pfizer sales management (and Pfizer Medical), representatives were to inform doctors the Lyrica control group experienced a 51% reduction in seizures as opposed to the Keppra control group which only experienced a 37% reduction in seizures. Not only were these studies not head-to-head, there was no evidence to suggest comparable dosing regimens, common study protocols, trial designs, or inclusion criteria. Because of the differences in trial designs, inclusion criteria and other factors, per *The Field Guide* and FDA regulations, it was "not permissible to compare results from two non-comparable trials."

207. Further, during a conference call with TSR's in October 2006 Pfizer Senior Sales Managers again instructed their sales representatives to emphasize the 51% vs. 37% seizure reduction as a means to tout Lyrica's improved "efficacy" as opposed to its competitor Keppra. Pfizer Medical also participated in this conference call and articulated the company's position that, while Pfizer sales representatives could not "officially" tell doctors that Lyrica was more

efficacious than Keppra, they could imply it by using the 51% vs. 37% seizure reduction rate information.

208. Pfizer thus engaged in a scheme of deliberate, misleading comparisons between Keppra and Lyrica when there were no such head-to-head studies available, in violation of Pfizer policy and FDA regulations

209. Moreover, by telling doctors Lyrica was more efficacious than Keppra, Pfizer was representing that the 51% reduction in seizures in Lyrica was across the board, meaning the same results would be experienced by *any* patient who was currently taking Keppra, even if that patient was taking Keppra for one of the seizure indications for which Lyrica was not approved.

C. USING SECONDARY ENDPOINTS TO OFF-LABEL PROMOTE LYRICA

210. One of the most aggressive off-label schemes developed shortly after the launch was the promotion of the "secondary endpoints" from several Lyrica studies and the unapproved uses of Lyrica from those studies. At the launch meetings in September 2005, Pfizer senior sales executives instructed its sales force, including Relator Farber, to market Lyrica's purported "secondary endpoints." These secondary endpoints had been mentioned in two Pfizer studies, *Dworkin*[57] and *Rosenstock*[58] as possible additional beneficial endpoints reached other than those intended in the study, including as a sleep medication and for its use in reducing anxiety and total mood improvement. These secondary endpoints indications are not FDA-approved. Put another way, the studies were false and misleading at best.

[57] According to the *Dworkin* study, the secondary endpoints included additional pain ratings, sleep interference, quality of life, mood, and patient and clinician ratings of global improvement.
[58] According to the *Rosenstock* study, the secondary endpoints included additional pain ratings, sleep interference, quality of life, mood, and patient and clinical ratings of global improvement.

VIII. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF RELPAX

211. As discussed above, Eletriptan hydrobromide, a prescription drug manufactured and marketed by Pfizer under the brand name "Relpax," was FDA-approved for treatment of acute migraine headaches in December 2002.

A. FALSE MARKETING OF RELPAX AS SUPERIOR: PROMOTION BASED ON UNSUBSTANTIATED REPRESENTATIONS

212. There is no claim of Relpax superior efficacy over other competitor drugs in the FDA-approved label for Relpax and has never been such a claim in the label. Nonetheless, Pfizer directed its sales force to claim that scientific data established Relpax's superiority over competitor migraine medications.

213. According to Relator Glenn DeMott, at a May 2003 national training sessions in Detroit, Pfizer presented its Relpax sales force present at the training with a visual presentation about Relpax. The presentation discussed other competitor drugs to Relpax. There was no discussion in the presentation of any test results showing that Relpax was superior to Imitrex (sumatriptan) or other competitor drugs. The presentation contradicted Pfizer's management's repeated and persistent oral and written claims of Relpax superiority to Imitrex.

214. Pfizer's Relpax marketing strategy involved extensive use of published research studies, particularly two articles authored by Dr. Giorgio Sandrini[59] and Dr. Ninan T. Mathew,[60] to claim that Relpax was superior to its competitor, Imitrex. Because the two Studies' conclusions about superiority had various deficiencies as to scientific method and/or analysis and

[59] G. Sandrini, M. Farkkila, G. Burgess, E. Foster, Haughie for Eletriptan steering committee, Eletriptan vs. Sumatriptan: A Double-Blind, Placebo-Controlled, Multiple Attack Study, published in *Neurology* 2002; 59:1210-1217.

[60] Ninan T. Mathew, M.D.; Jeam Schoenen,, M.D.; Paul Winner, D.O.; Nancy Muirhead, M.S.; Carolyn R. Sikes, Ph.D., Comparative Efficacy of Eletriptan 40mg Versus Sumatriptan 100mg, published in *Headache* 2003; 43:214-222.

involved claims of superiority that were not in the label, use of the Sandrini and Mathew Studies for comparing Relpax more favorably to Imitrex was off-label marketing and misbranding.

215. Pfizer's Relpax Business Team marketed the Sandrini Article as not to be used for promotion in the field. Nonetheless, Pfizer's sales managers directed representatives to use reprints of the off-label Sandrini Article directly with physicians.

216. The FDA investigator's report of August 5, 1999[61] examined the Sandrini study and another study by Dr. P.J. Goadsby[62] as part of the Relpax application for FDA approval. Authored by Randy Levine, M.D., the FDA report rejected comparative claims that Pfizer proposed as a result of the studies. Among the FDA report comments are:

- The evidence was not suggestive of a difference between 40 mg. [of Relpax] and sumitriptan.
- The efficacy of the drug was not shown t o be better than sumitriptan at doses with a similar adverse event profile.
- It does not appear to offer any advantages over approved 5HT1 agonists [triptans].
- Comparative trials with sumitriptan did not demonstrate a clear superiority and risk to benefit ratio.
- The studies did not provide adequate evidence that the drug was superior to sumitriptan.

217. The Sandrini Study was off-label, since it researched and discussed an initial Relpax dose of 80 mg., which is twice the FDA-approved initial dose

218. Another FDA researcher questioned the Mathew Study findings, including commenting that the research was not adequately controlled to be scientifically reliable. The Mathew Study failed to eliminate certain study participants who previously used Imitrex

[61] Levin, Randy, M.D., Neurology Team Leader, FDA Division of Neuropharmacological Drug Products, August 5, 1999, Subject: NDA 2016, Relpax (eleptriptan).
[62] P.J. Goadsby, Perrari M.D., J. Osesen, Eletriptan in acute migraine: a double-blind, placebo-controlled comparison to sumatriptan, *Neurology* 2000.

219. The Relpax label, as approved by the FDA, refers to the parts of the Sandrini and Goadsby Studies that compared Relpax to placebo. The Relpax label does not mention Relpax treatment compared to Imitrex treatment. That is, the comparative results of the Sandrini Study (identified with the FDA as #318) and the Goadsby Study (identified with the FDA as #314), which involved Imitrex, are not mentioned in the FDA-approved package insert. The Mathew Study results are not included in the label in any fashion. Without the Mathew Study and the Sandrini and Goadsby comparative results to Imitrex being in the label, Pfizer had no basis for marketing claims that Relpax was superior in efficacy to Imitrex.[63]

220. Prior to the national training meeting in May 2003, in Detroit, Michigan, Pfizer's training materials directed the entire Relpax sales force, including Relator, to promote Relpax by making false comparative claims of superiority to Imitrex. Pfizer's training materials were aimed at causing sales representatives to conclude that Relpax provided superior migraine pain relief when compared with Imitrex, at 2 hours after administration, even though the FDA had not permitted such comparative claims. The superiority claims were based on the studies by Dr. Sandrini and Dr. Mathew.

221. In November 2003, Pfizer distributed to its Relpax sales force a CD-rom that directed sales representatives to make false statements about Relpax's superior efficacy. The CD misrepresented study data from the Sandrini and Mathew studies and used the term "superior" to compare Relpax's efficacy with 100mg of sumatriptan (Imitrex). The sales presentation to be made by the Pfizer sales representatives was to include the message "Relpax is superior from start." The CD instructed sales representatives to tell physicians that Relpax's superior efficacy was in the label. The CD stated that Relpax's efficacy "appears in the U.S. label" and is "shown

[63] Amended Complaint at ¶¶172-75, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009

in the U.S. label." However, the comparative data claims are not in the label and the FDA investigators did not find that the superiority claims were adequately demonstrated by the research submitted.

222. During training sessions conducted November 19, 2003 to November 21, 2003, District Manager Krams trained sales representatives under his supervision to use Pfizer Medical and Drug Information proactively to show the superiority of Relpax over another competitor drug, Zomig® ("Zomig"). The Medical and Drug Information involved the efficacy of the Zomig nose spray and was marketed by Pfizer as "Not to be printed, reproduced, left behind or used in detailing." Both District Manager Krams and Regional Manager Steve Reese told sales representatives to use the document to promote Relpax as having a more effective response, significantly less recurrences of headaches, and significantly less use of alternative "rescue" medications, even though there was no FDA-approved basis for making such comparative claims of superiority over Zomig.[64]

223. In November 2003, Pfizer provided its Relpax sales representatives with a Relpax Plan of Attack Resources Guide that guided the representatives in ordering materials to be used to promote false claims of Relpax superiority to other competitor drugs.

224. In May 2004, to bolster its claims of Relpax superiority to Imitrex, Pfizer Regional Director Reese utilized a research article authored by Hans-Christoph Denier *et. al.*[65] The Denier Article was not independent scientific research, but was merely a summary of data from the flawed Sandrini, Mathew, and Goadsby Studies, discussed above. The Denier study combined primary and secondary endpoint data and contradicted the package insert that stated:

[64] Amended Complaint at ¶¶176, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).

[65] Hans-Christoph Denier, Robert Ryan, Wei Sun, Jayasena Hettiarachchi, The 40mg. Dose of Eletriptan; Comparative Efficacy and Tolerability Versus Sumatriptan 100mg., published in *European Journal of Neurology* 2004, 11:125-134.

> Comparisons of the performance of different drugs based on results obtained in different clinical trials is never reliable. Because studies are generally conducted at different times, with differing patient samples, investigators, criteria, and interpretations of the same criteria and under different conditions (dose, dosing regimen, etc), quantitative estimates of treatment responses and response timing maybe expected to vary considerably among studies…

225. Nonetheless, Mr. Reese insisted that the Denier Article conclusively established that Relpax was the only drug in the entire class of "triptan" drugs that was consistently superior to Imitrex.

226. In a May 2004 sales training session, Regional Director Reese, in a presentation to his subordinates that relied upon the Denier Article, declared that Relpax was superior and that the FDA had approved such comparative claims. District Manager Krams made similar claims of Relpax superiority and stated that the superiority claim had received FDA approval.

B. RELPAX SWITCHING EFFORTS

227. Pfizer sales representatives followed management directives and used various off-label and unapproved research articles in direct marketing to physicians in a Pfizer-approved "upgrade campaign" to switch patients from Imitrex to the newer Relpax.

228. Claiming superiority to Imitrex, Regional Director Reese, District Manager Michael Krams, and other Pfizer managers in or about August 2003 engineered sales activities to switch patients from existing drugs to the allegedly "superior" Relpax. Representatives were instructed to ask physicians' office staffs to compile lists of patients who had been treated for migraines. This often required Pfizer or the representative providing compensation to the physician's office for the work required to identify patients treated for migraines. The representative requested the information on patients who experienced migraines in order to solicit the patients to come to the physician's office for new "superior" migraine treatment—with Relpax. With the assistance of the Pfizer representative, or by the Pfizer representative entirely,

each such indentified patient was sent a letter encouraging a doctor's office visit to discuss a new migraine treatment.[66]

229. In 2004, Pfizer District Manager Krams directed sales representatives to obtain multiple Relpax coupons for free prescription from Pfizer's website. To accomplish this, sales representatives had to enter the names of patients, usually fake names fabricated by the representatives, to get the coupons. The coupon paid for the entire prescription. Then, as directed by District Manager Krams, the representatives called upon physician offices with high numbers of Medicaid patients and asked them to switch these patients to "superior" Relpax.

230. In or about June 2004, in order to switch patients to Relpax using false claims of superiority, Regional Manager Reese established competitions among the representatives to achieve the highest number of doctor office "switch campaigns." Mr. Reese urged each representative to conduct 20 or more such letter-writing campaigns each quarter. This effort was conducted in multiple regions and was highly successful in increasing the number of Relpax prescriptions.

231. Relator DeMott's final notes of his Pfizer regional training on November 19-21, 2003 also document a "switch campaign" by using the Farkkila Study. Relator gave these final notes to Relator's District Manager and Regional Manager. Relator's final notes were a combination of his own meeting notes, taken during the training, and those meeting notes that another representative authored and that Mr. Krams had approved. In the combined form, Relator's final meeting notes accurately reflect that the representatives were directed to advise physicians that the Farkkila Study showed that Relpax had high efficacy in a patient population that had failed to respond to Imitrex. However, the Farkkila Study actually stated the Study had

[66] Amended Complaint at ¶¶181-85, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).

a limitation because "the historical report of sumatriptan treatment failure was not confirmed by prospective treatment." The Study authors also pointed out that there was a "limitation" in the Study due to the "lack of a sumatriptan control group." According to the Farkkila Study's authors, if such an active Imitrex control group had been included and if the Relpax group showed statically significant better results as compared to the Imitrex control group, the Study results would have been much more useful. Thus, the Farkkila Study's conclusions are very limited and could be true for virtually any drug in the class.

232. On January 28, 2004, District Manager Krams directed Relator DeMott to post homemade "wellness check" forms in physician's offices. The "wellness check" asked patients 3 questions about their migraines. If the patient answered positively to any question, the patient was instructed to ask the physician about a new migraine medication.

233. Pfizer's efforts to switch patients to Relpax caused thousands of patients to visit their physicians under false pretenses and to obtain a prescription for a "superior" drug, which in fact was not proven superior to existing migraine medications.

234. Beginning in the summer of 2003 and continuing through October 2004, Pfizer implemented a policy and practice of encouraging physicians to prescribe Relpax and patients' to fill Relpax prescriptions, thereby increasing Pfizer's prescription drug market share and profits.

235. Pfizer used a purported clinical study scheme to generate Relpax sales involving the "Multiple Migraine Outcomes Study." Pfizer representatives provided physicians with patient literature and free Relpax samples, called "Challenge Kits." Physicians were told that they were participating in a clinical study and that it was urgent to have their patients use Relpax to participate. Pfizer sales representatives distributed samples that were not in appropriate FDA-approved, Pfizer-issued, labeled sampled packages. Instead, Pfizer sales representatives, at the

direction of their managers, relabeled samples and placed them in plastic bags issued by Pfizer's Relpax Product Business Team. Included on the outside of the bag was a Relpax prescription sticker that physicians could remove to affix to their own prescription pads. In order to "complete" the study, a patient had to fill the prescription and answer some questions. In return for filling the prescriptions and answering the questions, the patient received a "gift" from Pfizer's product business team. Pfizer District Manager Krams admitted that the purpose of this "study" was to increase Relpax prescriptions.

236. Well after Relpax's FDA approval, Pfizer's Relpax Business Team selected high-volume Medicaid prescribers throughout the nation to participate in a "study" where the physicians were paid large sums of money to place 3 patients on Relpax and compare the results with patients given placebos. One such physician was located on West Broad Street in Columbus, Ohio. The research representative of the independent research company Pfizer hired to conduct the "study" reported to Relator that it was a national program and that there were multiple test sites in Ohio and elsewhere that used high-prescribing physicians with only a few patients per site. These facts indicated to Mr. DeMott that the study was nothing more than a method to pay doctors who were high migraine-medication prescribers to gain experience using Relpax.

237. As part of its Relpax promotion activities, by June 2003, Pfizer instigated a speakers bureau program for physicians. Doctors were paid to travel to a free weekend "speakers" training session in a metropolitan hotel. Some speakers thus trained were never used as speakers, nor did Pfizer even intend them to make presentations on its behalf because they did not have the knowledge, professional status, or presentation skills to be speakers. In many

instances, the purpose of Pfizer's Relpax speakers bureau was not to recruit Relpax lecturers, but was primarily to influence the speaker's own prescribing habits.

238. District Manager Krams encouraged Relator DeMott and other sales representatives to recruit speakers on Relpax so that the speakers would write more Pfizer drug prescriptions, particularly Relpax. District Manager Krams directed one of his sales representatives to recruit Dr. Frank DiBenedetto, D. O. as a speaker and attend the Pfizer out-of-town expense-paid "speaker-training," without regard to his speaking ability or migraine expertise. Pfizer recruited Dr. DiBenedetto because he had a large Columbus, Ohio Medicaid patient practice and wrote a large number of migraine medication prescriptions. The speakers bureau recruitment was successful as Relator DeMott recounted that Dr. DiBenedetto thereafter was more receptive to his sales calls about Relpax and other Pfizer drugs.

239. According to Relator DeMott, on November 25, 2003, Pfizer provided prescription sales data to its sales force showing that the Columbus, Ohio Townstreet Clinic operated by the Royder family was responsible for writing about 80 Relpax prescriptions monthly. This Clinic was Pfizer's top Relpax prescriber in Mr. DeMott's sales territory and assisted Relator in being highly ranked for Relpax sales nationally. Dr. Palma, who worked at the Royder clinic, told Relator that his prescription practices were dictated by a "private formulary." Various Pfizer sales representatives and other pharmacy company sales representatives told Relator that kickbacks to Mrs. Royder and/or the Townstreet Clinic were made to ensure listings on the lucrative Townstreet formulary.

240. Pfizer also used a program to pay physicians $250 each, ostensibly to educate Pfizer sales representatives about Relpax on conference calls. In reality, the payment was a transparently disguised kickback designed to convince the physician to prescribe the drug. The

physicians were selected by sales representatives based on the volume of their practices and potential for increased prescriptions of Relpax. Pursuant to this program, Pfizer sales representatives were repeatedly "educated" on the very same clinical studies, including unapproved and off-label studies, by various physicians. The sales representatives participating in these conference calls were instructed to pretend that the physician was presenting new material to them and to ask questions as if they were hearing the information for the first time. On several of these fake "educational briefings" in which Relator participated, the speaker failed to give any organized presentation at all, but thanked Pfizer for the opportunity to participate in the program. Pfizer instructed sales representatives to contact physicians a few days after their so-called "educational briefings" to inquire whether the physicians prescribed more Relpax after giving presentations.

241. Pfizer began paying physicians according to the scheme outlined above in January 2004. Relator DeMott recalled personally participated in about 10 of these fake conference calls and believes there were others between January and June 2004. When Mr. DeMott asked District manager Krams to discontinue the calls, Mr. Krams replied that "the whole region was doing them" and therefore they were unlikely to be sanctioned for the practice.

242. Still another program of unlawful kickbacks began in the summer of 2003 and continued through October 2004. Under this program, Pfizer recruited various physician specialists to accompany Pfizer sales representatives to particular family medical practices or general practitioner offices, with the hope of gaining more referrals from these practitioners. To accommodate these physician specialists and increase Relpax prescriptions written by these specialists, Pfizer organized another sham education program whereby these physician specialists were paid $500 to $750 per visit to accompany representatives on sales calls and

deliver educational presentations to the family or general practitioners' offices. These "educational presentations" were, however, thinly-veiled introductory and matchmaking services provided by Pfizer to the physician specialists in exchange for increased Relpax prescriptions.

243. Senior Pfizer representative informed Mr. DeMott that, although he did not participate in this presentation program himself, these educational presentations were common in Pfizer's Cluster X, the other half of Pfizer's sales force. Indeed even after an internal company memorandum was written and circulated within Pfizer directing that these activities by terminated, Relator was aware of ongoing violations with the use of the speakers programs through December 2006.[67]

C. UNSOLICITED MEDICAL AND DRUG INFORMATION

244. At Pfizer's August 27, 2003, District mid-year POA meeting, District Manager Krams told the Pfizer sales representatives to use Medical and Drug Information for marketing Relpax, in violation of FDA law and the Neurontin CIA. Regional Director Reese announced that Pfizer researchers were publishing clinical papers comparing Relpax with competitor drugs, including Amerge®, Zomig®, and Maxalt®, as well as a Relpax, cardiovascular study. Some of these studies did not in fact exist. Sales representatives were directed to send Pfizer Medical and Drug Information to physicians without obtaining physician requests for the information, in order to expand the use of Relpax

245. During the summer of 2004, in an effort to boost Relpax sales, Pfizer Representative, Grandee Trout, sent packages of scientific research articles about Relpax to physician's offices, which were marked by Pfizer as "Do not show to physicians." Relator

[67] Amended Complaint at ¶¶186-212, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).

DeMott and others reported this conduct and management's failure to take action about it to Pfizer's compliance and human relations department.

IX. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF LIPITOR AND NORVASC

A. PFIZER'S OFF-LABEL PROMOTION OF LIPITOR AND NORVASC THROUGH FLAWED STUDIES AND FALSE ADVERTIZING

246. Over the years after launch in 1997, Lipitor had no "outcomes data" (data that showed that Lipitor reduced morbidity and mortality), nor approval for use in diabetic or atherosclerotic patients. After experiencing small revenues mainly because of competitor drugs and lack of outcomes data, Pfizer has launched a substantial marketing campaign in early 2003. The strategy depended on off-label promotion, kickbacks and incentives and heavy sampling.[68]

247. In order to boost Lipitor's revenues and thwart the competition, Pfizer's objective was to target "specific patient types," namely diabetics, atherosclerotic, and hypertensive patients. Pfizer's promotional materials and slides detailed their strategy, which was to market the drug off-label and offer incentives and kickbacks to healthcare providers.[69]

248. To promote Lipitor off-label, Pfizer used the results of three studies to tout Lipitor's performance for the treatment of hypertensive, diabetic and atherosclerotic patients, which had not been submitted to the FDA for approval prior to its marketing , nor had it ever been approved by the FDA.[70] Not only were these studies flawed due to small patient populations, but also showed no significant advantage for treatment in diabetic patients.

249. Pfizer marketed Lipitor for treatment of diabetics and atherosclerotic patients, in both cases claiming that Lipitor reduces the number of heart attacks and strokes in these patients.

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[68] Complaint at ¶64, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).
[69] *Id.*
[70] *Id.* at ¶63.

In fact, diabetic patients are at a much greater risk of a heart attack or stroke than a hypertensive patient, and bypass surgery and angioplasty are the traditionally accepted therapy for cardiac patients who suffer from diabetes. Using Lipitor for the treatment of such at-risk patients effectively leaves these diabetic patients untreated. Moreover, diabetic patients are at higher risk for liver damage for Lipitor. [71]

250. Moreover, Pfizer has used such unapproved studies and materials not only to promote Lipitor, but also to promote Norvasc. For instance, in advance of the POA 2 meeting in 2003, Norvasc Disease Management Team ("DMT") distributed multiple copies of a handout marked "do not detail" to its sales force, including to representative Blair Collins. The expressed purpose of the handout was to provide:

> "new opportunities to use pieces based on ALLHAT [a recent study]. We have provided you with this not-for-detail sheet to give you some direction while discussing the relevance of this invaluable study. Please add this sheet to your Playbook as you compile your resources for this POA."

As with other such pieces, Mr. Collins and others used paper cutters supplied by District Managers and others at the POAs to trim the "do not detail" language off the handouts before putting them in their detail books. In other instances Pfizer would distribute "do not detail" materials that were fold outs-on those, the design enabled the sales representatives to fold the flaps over and conceal the "do not detail" language, and that I what they did, prior to placing it in their detail books.[72]

[71] Complaint at ¶¶70-74, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).
[72] *Id.* at ¶¶102-03.

B. PROMOTION OF LIPITOR AND NORVASC FOR OFF-LABEL USES BY PAYING "THOUGHT LEADERS"

251. Pfizer' promotional slides dated August 14, 2003 also show the company's intent to buy reputations of "Super KOLs" or National Key Opinion Leaders and have them promote Lipitor off-label for the reduction of cardiovascular events in the diabetic and atherosclerotic patients to regional Cardiovascular Key Opinion Leaders who would in turn promote Lipitor off-label to local cardiologists who would then be paid to promote Lipitor off-label to local family practice and internal medicine specialists. As stated in Blair Collins' Whistleblower complaint, Pfizer knew that Lipitor was not, and would not be, approved by then to reduce cardiovascular events in this very difficult to treat patient population, and even though the outcomes data was not yet approved.[73]

252. Pfizer's use of studies for off-label marketing of Lipitor since early 2003 shows a pattern of conduct and behavior on a national scale. Based in part on this unapproved literature, physicians have prescribed Lipitor for patients for whom Lipitor is not proven safe or effective and indeed may be dangerous."[74]

X. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF ZITHROMAX

253. Despite the fact that Zithromax is not indicated to treat sinusitis and is not proven to be effective in treating sinusitis (because the drug does not penetrate the sinusoidal cavities like it does the lung tissue), Pfizer directed sales representatives like Blair Collins to promote/sell Zithromax off-label for sinusitis.[75]

254. Though Zithromax has never been approved to treat sinusitis but is indicated to treat the bacteria that causes sinusitis, Pfizer instructed Blair Collins and other sales

[73] *Id.* at ¶93.
[74] *Id.* at ¶101.
[75] Complaint at ¶¶104, 105, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

representatives to detail and sell of their Allergists, ENT's, Internal Medicine Specialists, Family Practice physicians, Pediatricians and Emergency Room physicians on this off-label use. [76]

255. Moreover, Pfizer's sales representatives were instructed on how to market Zithromax off-label, and how to respond to doctor's questions and concerns regarding its unapproved status for treatment of sinusitis. Specifically, representatives were instructed to respond that "studies are so expensive and difficult that Pfizer would not seek approval for sinusitis until the expiration of Zithromax' patent." In response to a doctor's concern that Zithromax was not effective for their sinusitis patient, but that another antibiotic like Augementin or Ceftin were effective for this treatment, the representatives were instructed to state that "antibiotic resistance must be growing and therefore it wouldn't matter which medicine is used first, because the patient would require two antibiotics to get better. The sales rep would add, however, that one of antibiotics should be Zithromax."[77]

256. Off-label detailing and promotion of Zithromax for sinusitis has caused patients to over pay for an expensive and ineffective treatment of sinusitis. About 35 percent of the antibiotic prescriptions written in the United States are for sinusitis. Accordingly Mr. Collins estimates that about 35 percent of the prescriptions of Zithromax, and virtually all of the summertime prescriptions of Zithromax, have been for sinusitis. [78]

XI. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF ZOLOFT

257. Zoloft was first approved by the FDA in about 1991, for the treatment of depression in adults. Since then, the FDA has also approved Zoloft for use in treating obsessive compulsive disorder, panic disorder, post traumatic stress disorder, premenstrual dysphoric

[76] *Id.* at ¶106.
[77] *Id.* at ¶107.
[78] Complaint at ¶¶109-10, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

disorder, and social anxiety disorder. However, out of all of the approved indications, the ***only one approved for treatment of children and teenagers is obsessive compulsive disorder.***

258. Over the years, Pfizer has engaged in systematic and aggressive marketing and promoting the use of Zoloft in children and adolescents, including at the highest "approved dose." Pfizer has also misleadingly suggested in its 2006 Annual Report- that the drug is more broadly indicate for children than is true. Pfizer's off label marketing methods included marketing Zoloft to ***pediatricians,*** family physicians and internal medicine doctors.[79]

259. Due to serious public health concerns and safety issues involved in the use of antidepressants such as Zoloft by children and teenagers which cause suicides, suicidal attempts, suicidal ideation, and self-mutilation, the FDA took action in 2004, ordering antidepressant manufacturers like Pfizer to put a "black box" warning on drugs to alert doctors, parents and patients that the drugs increase these serious risks among children and teens. Moreover, in April 2007, the FDA increased the age under the Black Box warning on these antidepressants to 25 years. Furthermore the Journal of the American Medical Association analyzed around 27 studies in favor of Pfizer and other manufacturers and concluded that one ***could not show that any antidepressant was even effective in treating children*** (age 12 and under) for major depression.[80]

260. Notwithstanding the serious implications involved in the use of Zoloft by children, Pfizer has marketed Zoloft through various sales divisions to sell Zoloft, Zyrtec and Zithromax to pediatricians, allergists, and ob/gyn's (i.e. Zoloft for patients with PMS and Zithromax for patients with Chlamydia trachomatis and gonorrhea). Because Zoloft was not sold

[79] Complaint at ¶¶111,112 *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).
[80] Complaint at ¶¶113,114, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

to allergists, the sales representatives had to rely on marketing to pediatricians to make quota on Zoloft.[81]

261. Sales representative Blair Collins had explained that he went on "field rides" with an Institutional Healthcare Representative (IHR) Ken Smith to promote Zoloft for various off-label uses to pediatricians, family practitioners and ob/gyns in Texas. On these field rides, Mr. Collins has heard Smith say many times that the pediatricians and family practice physicians should look for and recognize the symptoms of depression in children and adolescents. "These symptoms could include the feelings that ensue when a girl tried out for, but did not make cheerleader, or a boy who tried out for did not make the football or basketball team, and that these physicians should especially watch for elementary school children who may have hard time making new friends or be frustrated in class with teachers or with peers. Smith said words to the effect that: "these were the children who should be on Zoloft.[82]

262. Moreover, Mr. Smith indicated that Zoloft should be tried for two to three weeks at 50 milligrams, despite his knowledge that Zoloft takes at least six weeks to regulate a person's feelings and moods and that to titrate at two to three weeks was too early. However, such representations were made to fulfill Pfizer's desired goal of getting patients to take up to 100 milligrams and to keep them there, despite the fact that Zoloft was ***not*** indicated to treat children with depression at any dosage.[83]

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[81] Complaint at ¶¶116, 117 ,*United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).
[82] *Id.* at ¶ 117
[83] Complaint at ¶117 *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

XII. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF DEPO-PROVERA

263. As discussed above, Medroxyprogesterone, an injectable liquid contraceptive that Pfizer manufactures and markets under the brand name "Depo-Provera," was approved by the FDA on October 29, 1992 for use as a contraceptive to prevent pregnancy.

264. The Depo-Provera contraceptive injection is typically administered by a physician, a physician's assistant, or registered nurse once every 3 months. Each vial of liquid contains one 3-month dose.

265. For years, Pharmacia, Pfizer's predecessor, trained and encouraged its district managers and sales representatives to "do deals" and "barter" with physicians and medical institutions by offering large quantities of drug samples (what Pfizer now calls "starters") in exchange for large or standing orders for those or other drugs. In some deals, physicians paid for 100 to 300 units of Depo-Provera valued at $1250 to $3750. This bartering occurred in multiple states. In the end, managers and representatives were striking deals with state Medicaid departments to get much larger purchases and thereby dramatically increase their bonuses.

266. During a Pfizer sales meeting held in or around August 1998, Pfizer sales representatives revealed that they were engaging in "deals," whereby the representatives provided physicians with free samples of Depo-Provera in exchange for large and standing orders of Depo-Provera or other drugs.

267. At this time, Mr. Glenn DeMott informed his Pfizer District Manager, Gary Grote, of the deals and specifically quoted the applicable passages of company compliance manuals of Pharmacia, Pfizer's predecessor, expressly prohibiting such practices. At Mr. Grote's instruction, Mr. DeMott gave a presentation the next day on a conference call with all sales representatives in the district, in which he informed them that soliciting business or

otherwise engaging in such deals using free samples was improper. Mr. Grote ended the call by announcing that the inappropriate use of samples would lead to termination of employment. Very shortly after this call, Mr. Grote was promoted to a position in corporate contracting and David Musci became Glenn's District Manager.[84]

268. In the Spring of 1999, Glenn DeMott received several telephone calls from sales representative in Kentucky, who stated that their District Manager, Naomi Paziorko of Louisville, Kentucky, encouraged them to provide samples in exchange for sales. Specifically, these representatives promised physicians 3 free doses of Depo-Provera for every 3 orders of prescription drug Estring. He informed these representatives that such deals were illegal.

269. On the day after the conversations with the Louisville, Kentucky area .representatives about inappropriate Depo-Provera deals, DeMott received a call from the District Manager, Ms. Paziorko, in which she ordered him to stop interfering with her sales representatives. He quoted to her the compliance manual provisions stating that these kinds of dealings were illegal, to which Ms. Paziorko repeated that Mr. DeMott was to stop talking to her sales representatives. Ms. Paziorko told representatives not to talk to him. According to Mr. DeMott, Pfizer took no action to stop these improper deals and the unlawful sampling practice continued.

270. According to Mr. DeMott, Pfizer's deals with Depo-Provera samples was a nationwide scheme that expanded far beyond the Estring deals initially used. Mr. DeMott recounted in his complaint a fall of 1999 telephone conversation with a senior sales representative in Portland, Oregon who reported that district representatives in Oregon were engaging in similar schemes of sample dealing in order to make their sales quotas, including

[84] Amended Complaint at ¶¶213-33, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).

frequently giving up to 50 samples or more to induce large purchases, very similar to the trades in Glenn DeMott's region.

271. According to Mr. DeMott, the bartering and dealing practices continued in his own sales district even after he was directed to conduct a conference call presentation to his district sales representatives advising them about the impropriety of doing these dales. In the Fall of 1999, a sales representative in that district informed Mr. DeMott that he had to continue doing the Depo-Provera deals, "in order to keep my numbers up." After this sales representative left Pfizer, Mr. Musci informed Mr. DeMott that as District Manager, Mr. Musci felt compelled to "honor" a large deal that had been arranged before the sales representative had left the company and accordingly delivered 65 free sample vials of Depo-Provera to a heavily prescribing doctor's office in Dayton, Ohio.

272. According to Mr. DeMott's complaint,[85] a female Pfizer sales representative from Dayton, Ohio, informed him that she was managing the former sales representative's accounts and that several accounts demanded sampling deals in order to make purchases of Depo-Provera because, as these offices explained, that is the way they did business with prior representatives. At least two doctor's offices discontinued their business with the Dayton sales representative and denied her any further access to their offices when she refused to continue making Depo-Provera deals using "free" samples.

273. Rather than prohibit the ongoing Depo-Provera "deals" within the region, Pfizer management encouraged and thereby perpetuated these schemes by training newer representatives to conduct deals with Depo-Provera. For example, Mr. DeMott recounted that in the Fall of 1999, he had contacted a sales representative based in Lancaster, Ohio, who reported

[85] Amended Complaint at ¶¶213-233, *United States, et al. ex rel. Glenn DeMott v. Pfizer, Inc.,* Civ. No. 05-12040 RWZ (D. Mass. Apr. 17, 2009).

that his District Manager, Gregory Clark, was training representatives in his district to make deals with Depo-Provera samples to obtain large orders of Depo-Provera.

274. Relator DeMott reported the Depo-Provera dealing as violations of company policy and federal law to his superior, David Musci, on at least two separate occasions during the fall of 1999 and the beginning of 2000, but received no response from management. Mr. DeMott further recalled that a Pfizer sales representative told Relator that when they asked their district managers about the illegality of the deals, the managers responded that they needed to do whatever was necessary to get Depo-Provera business

275. Based on the various reports Relator DeMott received from his and other districts within his region and based on the company's nationwide response, dealing in Depo-Provera samples was a widespread practice beginning in 1997. The dealing of Depo-Provera did not end until April 15, 2003, the effective date of the Pfizer purchase of Pharmacia. To Relator Demott's knowledge only at that point did Pfizer take steps to end the sales of Depo-Provera to physicians through the Pfizer sales representatives and managers.

276. Pfizer concealed this unlawful conduct by, among other actions, failing to disclose that it was engaged in illegal off-label marketing and the payment of kickbacks to physicians and failing to take appropriate actions when Mr. DeMott made Pfizer's management and compliance officers aware of the violations described in this Complaint.

XIII. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF ZYRTEC

277. Zyrtec's indications have been approved for treatment of seasonal allergic rhinitis, perennial allergic rhinitis, and chronic urticaria (hives and pruritus). Zyrtec was initially approved in 1995 only for use in adults. In 1998, however, it was also approved for use in

children 24 months and older for seasonal allergic rhinitis and for children 6 months and older for the two other indications.

278. Zyrtec has become a widely prescribed medication, and between one quarter and one half of all prescriptions are for pediatric patients. The revenue growths have been demonstrated by Pfizer's April 19, 2005 SEC filing which states that for the first quarter of 2005, Zyrtec revenue reached $342 million dollars, growing by 14 percent compared to the same period in 2004. This growth occurred despite the fact that by mid 2004, FDA required Pfizer to change the label on Zyrtec to acknowledge some "additional rare, but potentially severe adverse events" that had been reported in the post marketing experience. These events included: "aggressive reaction, anaphlyaxis, cholestasis, convulsions, glomerulonephritis, hallucinations, hemolytic anemia, hepatitis, orofacial dyskinesia, severe hypotension, stillbirth, *suicidal ideation, suicide* and thrombocytopenia." [86]

279. Pfizer promoted Zyrtec for off-label by, among other things, detailing doctors with articles that were not approved for detailing and that in some cases provided incomplete and misleading comparisons of Zyrtec and one or more other drugs. Pfizer encouraged the sales representatives to tout Zyrtec's safety despite its knowledge about the reported post marketing side effects.[87]

280. As set forth in more detail in Blair Collin's Whistleblower complaint, Pfizer used unapproved articles and price lists influenced doctors, especially pediatricians, family doctors and internists to prescribe Zyrtec over competitor drugs.[88]

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[86] Complaint at ¶¶123,124, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).
[87] *Id.* at ¶125.
[88] Complaint at ¶¶125-28 *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

XIV. PFIZER'S ILLEGAL SALES, MARKETING, AND PROMOTION OF VIAGRA

281. In 1998, Viagra was approved by the FDA for only one indication: erectile dysfunction. The same is true today. After its launch by Pfizer, Viagra reaped tremendous profits, and as early as 1999, Pfizer engaged in off-label promotion of this drug due to the pressure to meet higher quotas because of Viagra's tremendous success.

282. Pfizer began marketing Viagra for use in women, selling to physicians such as obstetricians and gynecologists, and using such specialists to sell to other doctors who treat women including ob/gyns, and internal and family medicine doctors. This was done despite the fact that such promotion was off-label, and despite the fact that Viagra had never been appropriately tested in women.[89]

283. Moreover, the head of Ob/Gyn studies at University of Arizona Medical Center, (who also happened to be a brother of one of Pfizer's Regional Managers) often spoke at a serious of programs sponsored by various sales divisions of Pfizer regarding Viagra's use in women. He would say words to the effect of "Viagra has not been approved for treatment in women, but we find at the University of Arizona Medical Center, in our patients, that Viagra increases the intensity of orgasmic sensation, and it further seems to eliminate anorgasmia, or the inability of women who are either post-menopausal or who are being treated with an SSRI like Prozac or Zoloft and do not feel orgasmic sensations as often or as intensively as they once did."[90]

284. Pfizer's unlawful efforts proved to be very fruitful. At a meeting attended by Mr. Collins in May 2003, the opening remarks of John Woychick (the Senior Vice President of Sales for Pfizer's Pharmaceutical's Cluster X), included a run down of quota attainment for all Cluster

[89] *Id.* at ¶¶130,131.
[90] *Id.* at ¶¶132-133.

X medicines. During the meeting he proudly announced that Viagra prescriptions had increased with all specialists, and he laughingly said words to the effect of: "but no specialist is writing Viagra more often than the Ob/Gyn's."[91]

XV. FRAUDULENT CONCEALMENT AND TOLLING OF LIMITATIONS PERIOD

285. The Pfizer Defendants have concealed from the public the details of their underlying fraudulent and other illegal conduct not only during the time that they engaged in that conduct so as to avoid detection and cessation of their ill-gotten profits, but even to this day to avoid public scrutiny, any concomitant negative perception of their business, and liabilities to Plaintiff and members of the Class resulting from civil litigation.

286. Plaintiff had no knowledge of any of fraud or fraudulent schemes, illegal sales and marketing programs and conduct, kickbacks, bribery, payments or provision of illegal remuneration, conspiracies and concerted activities, illegal promotional activities, or other unlawful conduct alleged herein with respect to the Subject Drugs, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence, until the earliest date of September 2, 2009 when the above mentioned Settlement was announced and when the federal government filed its criminal Information and the DOJ issued its Press Release reporting on the resolution of the several criminal and civil allegations.

287. Plaintiff could not have discovered the unlawful conduct alleged herein at an earlier date by the exercise of due diligence because of the deceptive practices and techniques of secrecy employed by all of the Defendants and their co-conspirators to avoid detection of, and to conceal, their unlawful conduct and conspiracies.

[91] Complaint at ¶137, *United States ex rel. Blair Collins, et al. v. Pfizer, Inc.,* Civ. No. 04-11780 DPW (D. Mass. Aug. 13, 2007).

288. By reason of the foregoing, the claims of Plaintiff and members of the Class are timely under any applicable statute of limitations (as tolled by the filing of this Class Action Complaint) pursuant to the discovery rule and the doctrine of fraudulent concealment.

289. The Defendants have been aware of their unlawful conduct and conspiracies since the inception of such conduct. To this day, however, despite Defendants' awareness of their unlawful conduct, their knowledge of the federal investigation of relevant conduct and now their resolution of the charges by the United States of America, the Defendants continue to conceal from the public, including Plaintiff and the Class, the full details of their unlawful conduct.

290. The Defendants' failure to properly disclose their unlawful conduct and conspiracies, and other acts and omissions as alleged herein, was and is willful, wanton, malicious, outrageous, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of Plaintiff and members of the Class.

XVI. CLASS ACTION ALLEGATIONS

291. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiff brings this action on behalf of himself and a Class, defined as:

> All individuals in the United States and its territories who, for purposes other than resale, purchased, Geodon, Zyvox, Lyrica, Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zytec from at least January 1, 2001 through at least October 31, 2008.

292. Plaintiff also brings this action on behalf of himself and a Massachusetts Subclass ("MA Subclass") defined as:

> All individuals in Massachusetts who, for purposes other than resale, purchased, Geodon, Zyvox, Lyrica, Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zytec from at least January 1, 2001 through at least October 31, 2008.

293. Plaintiff also brings this action on behalf of a Second Subclass ("49 States Subclass") defined as:

> All individuals in the United States and its territories, excluding Massachusetts, who for purposes other than resale, purchased, Geodon, Zyvox, Lyrica, Aricept, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, Zytec from at least January 1, 2001 through at least October 31, 2008.

294. Excluded from the Class and all subclasses are (a) Defendants and any entities in which any Defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors and (b) any co-conspirators (including, among other, insurers with whom Defendants directly negotiated about aspects of the fraudulent scheme and conspiracy). Also excluded from the Class are any judges or justices to whom this action is assigned, together with any relative of such judge(s) or justice(s) within the third degree of relationship, and the spouse of any such person.

295. Plaintiff contends that this suit is properly maintainable as a class action pursuant to Rules 23 (b)(1), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure.

A. NUMEROSITY

296. The Class consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). Plaintiff is unable to provide an approximation of the number of potential class members, but notes that the dollar sales amount of the Pfizer Defendants was in the hundreds of millions. The disposition of the claims of the Class members in a single class action will provide substantial benefits to all parties and to the Court

B. TYPICALITY

297. The claims of the representative Plaintiff are typical of the claims of the Class, as required by Rule 23(a)(3), in that Plaintiff, like all Class members, purchased Defendants'

Subject Drugs. Like all Class Members, Plaintiff was damaged by Defendants' misconduct, in that, among other things, they purchased Subject Drugs to treat a condition while Defendants were actively engaged in their fraudulent marketing, promotion and sales scheme and conspiracy.

C. COMMON QUESTIONS OF LAW AND FACT

298. The factual and legal bases of Defendants' fraudulent marketing, promotion and sales scheme and conspiracy are common to all members of the Class and represent a common thread of misconduct resulting in injury to Plaintiff and all members of the Class.

299. Questions of law and fact common to Plaintiff the Class abound in this case, and those questions predominate over any questions affecting individual Class members, within the meaning of Rule 23(a)(2) and (b)(3). These common questions of law and fact include, but are not limited to, the following:

(a) Whether Defendants engaged in the fraudulent marketing, promotion and sales scheme and conspiracy alleged herein;

(b) Whether the conspiracy was implemented;

(c) Whether Defendants used kickbacks, bribes and/or other payments or provision of illegal remuneration or inducements to induce physicians and other healthcare providers to prescribe, administer, or otherwise treat patients with any of the Subject Drugs, whether or not such prescribing, administration or treatment was for medical conditions that were FDA-approved;

(d) Whether Defendants engaged in a fraudulent and/or unfair and deceptive scheme of improperly marketing, promoting and selling any of the Subject Drugs for durations of use or in dosages that exceeded or were otherwise outside the scope of FDA approval or that were not medically safe, efficacious, effective or useful;

(e) Whether Defendants coached or instructed physicians or others on how to conceal the off-label nature of the Subject Drugs on claim forms submitted by or to patients and members of the Class or the federal government;

(f) Whether Defendants prepared, funded and published studies and other materials which contained false information and misrepresentations concerning the safety and efficacy of the Subject Drugs;

(g) Whether Defendants prepared, funded and published studies and other materials which contained false information regarding off-label uses, or the validity of or propriety of or scientific and other support for, off-label uses of the Subject Drugs;

(h) Whether, and on how many occasions, Defendants provided false information and made false statements to the federal government regarding their sales and marketing scheme pertaining to the Subject Drugs;

(i) Whether Defendants utilized others and/or engaged in conspiracies to assist in the publication and dissemination of false statements, or fraudulent studies, to physicians concerning the safety and efficacy of the Subject Drugs;

(j) Whether Defendants engaged in a pattern and practice with the intent of deceiving and defrauding Plaintiff and the Class and with the intent of suppressing the unlawful conduct and conspiracy;

(k) Whether Defendants violated Massachusetts's or any other state's consumer protection statute;

(l) Whether Defendants are liable under state conspiracy and/or state concert of action and/or state aiding and abetting/facilitating laws;

(m) Whether Defendants unjustly enriched themselves at the expense of Plaintiff and members of the Class;

(n) Whether Defendants' illegal bribes, kickbacks, payments of illegal remuneration and/or other illegal inducements provided to physicians and other medical providers directly and proximately caused Plaintiff and members of the Class to pay for any of the Subject Drugs, or to pay more for the Subject Drugs than they otherwise would have paid either for those specific Subject Drugs or for an alternative drug or treatment which was more efficacious;

(o) Whether Plaintiff and the Class are entitled to compensatory damages, and, if so, the nature of such damages;

(p) Whether Plaintiff and members of the Class are entitled to punitive damages, treble damages or exemplary damages and, if so, the nature of such damages;

(q) Whether Plaintiff and members of the Class are entitled equitable relief pursuant to their claim for unjust enrichment or otherwise; and

(r) Whether Plaintiff and members of the Class are entitled to an award of reasonable attorneys' fees, prejudgment interest, post-judgment interest and costs of suit.

D. ADEQUACY

300. Plaintiff, M.A.C., by and through his mother Karen Caltieri, will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiff has retained counsel with substantial experience and expertise in the prosecution of both statewide and nationwide class actions. Plaintiff and his counsel are committed to the vigorous prosecution of this action on behalf of the Class and have the financial resources to do so. Neither Plaintiff nor counsel have any interests adverse to those of the Class.

E. SUPERIORITY

301. A class action is superior to other available methods for the fair and efficient adjudication of the controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves resources of the courts and the litigants, and promotes consistency and efficiency of adjudication.

302. The prosecution of separate actions by or against individual members of the plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for the Defendants which would, as a practical matter, be dispositive of the interests of

the other class members not parties to the adjudications or would substantially impair or impede their ability to protect their interests.

303. Defendants also have acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate declaratory and injunctive relief with respect to the Class as a whole.

XVII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Violation of Massachusetts General Law Ch. 93A, et seq.

304. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

305. Plaintiff brings this claim on behalf of himself and the MA Subclass.

306. Plaintiff and the MA Subclass are consumers who purchased Subject Drugs for personal use. Massachusetts has enacted laws to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. Massachusetts allows consumers a private right of action under such laws.

307. Through illegal, unfair, immoral, and unethical marketing of the subject drugs, and other previously described conduct and practices, the Defendants caused Plaintiff and the MA Subclass to purchase ineffective subject drugs instead of alternative drugs which were cheaper and more effective.

308. This conduct constitutes unfair methods of competition and unfair acts or practices in the conduct of any trade or commerce within the meaning of Massachusetts General Law Ch. 93A, et seq., and warrants the application of the laws of Massachusetts to all Defendants in this Court.

309. As a result of the Defendants' unfair acts and practices, Plaintiff and the Class suffered damages because they paid for subject drugs that were ineffective, paid more for the subject drugs than they would have paid for cheaper and more effective alternatives, and were denied effective treatment for their medical conditions while they were prescribed the subject drugs.

310. As part of their guilty plea and payment of fines and money for civil liabilities, Defendants Pfizer and Pharmacia agreed to pay substantial sums of money to the states, including Massachusetts. Such admission of liability and payment of civil liabilities to the states warrants the application of the laws of Massachusetts to all Defendants in this Court.

311. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, including Massachusetts, Plaintiff and the Class have and will continue to suffer damages in an amount to be determined at trial.

312. On September 4, 2009, plaintiff sent a demand letter pursuant to Mass. Gen. Laws Ch. 93A § 9(3) to: Defendants.

WHEREFORE, Plaintiff, M.A.C., by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

SECOND CLAIM FOR RELIEF
Violation of Consumer Protection Statutes
of the Remaining 49 States, District of Columbia and Puerto Rico

313. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

314. Plaintiff brings this claim on behalf of the 49 States Subclass.

315. Plaintiff and the Class are individual consumers who purchased Subject Drugs for their own personal use or for the personal use of those on whose behalf they have purchased

the Subject Drugs. All 49 of the remaining states, the District of Columbia and Puerto Rico have enacted statutes to protect consumers against unfair, unconscionable, deceptive or fraudulent business practices, unfair competition and false advertising. Most states allow consumers a private right of action under these statutes.

316. By the actions and failures to act of Defendants, including the above-described unlawful marketing schemes, kickbacks, bribes, payments and provision of illegal remuneration and inducements, omissions, concealment, and non-disclosure of material facts as alleged above, the Defendants deceived, and continue to conceal their deception of consumers such as Plaintiff and members of the 49 States Subclass. This conduct constitutes unlawful, unfair, and unconscionable business practices within the meaning of consumer protection statutes of the remaining 49 states, the District of Columbia and Puerto Rico.

317. Defendants directly and proximately caused Plaintiff and the Class to suffer damages by, as described above, paying or otherwise providing to physicians and other health care providers kickbacks and bribes as inducements for them to prescribe, administer, or otherwise treat patients with the Subject Drugs that are the subject of this action, whether for off-label uses or otherwise. Such conduct was directed to and induced physicians and other healthcare providers, and affected their patients and other consumers, including Plaintiff and members of the Class, who paid for the Subject Drugs, throughout the remaining 49 states, the District of Columbia and Puerto Rico. Such conduct is actionable under the consumer protection statutes of these jurisdictions. As a direct and proximate result of Defendants' conduct, Plaintiff and the 49 States Subclass have suffered damages in an amount to be determined at trial, and are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit, and any other damages provided under these statues.

318. Additionally, in prescribing, administering or otherwise treating patients with the Subject Drugs, physicians relied upon Defendants' above-described representations, omissions, non-disclosures and concealment of material facts, and other conduct regarding the safety and efficacy of the Subject Drugs. Such conduct was directed to, and acted upon by, physicians and healthcare providers, and affected their patients and other consumers, including members of the 49 States Subclass who paid for the Subject Drugs, throughout the remaining 49 states, the District of Columbia and Puerto Rico. Such conduct is actionable under the consumer protection statutes of these states, districts and territories. As a direct and proximate result of Defendants' conduct, members of the 49 States Subclass have suffered damages in an amount to be determined at trial, and are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit, and any other damages provided by these statutes.

WHEREFORE, Plaintiff, M.A.C., by and through his mother Karen Caltieri, on behalf of the 49 States Subclass, respectfully seeks the relief set forth below.

THIRD CLAIM FOR RELIEF
Conspiracy/Concert of Action

319. Plaintiff incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

320. Plaintiff brings this claim on behalf of himself and the Class.

321. Beginning at least as early as January 1, 2001, the exact date being unknown to Plaintiff and the Class, and continuing thereafter through at least February October 31, 2008, Defendants acted in concert with one another, with physicians and healthcare providers, and with other co-conspirators as described above, in a continuing conspiracy and/or concerted action to violate federal and state laws and to defraud Plaintiff and the Class by causing Plaintiff and the Class to purchase the Subject Drugs that had been prescribed to them due to kickbacks, bribes

and payment or provision of illegal remuneration or other inducements to the prescribing physicians. In the absence of Defendants' conspiracy, Plaintiff and the Class would not have been prescribed these Subject Drugs and would not have been exposed to/and suffered from their related side effects. Further, in the absence of this conspiracy and/or concerted action, Plaintiff and the Class would not have purchased these Subject Drugs or would have paid much less for other drugs or alternative treatments which would have been more beneficial in treating their conditions.

322. Additionally, as discussed above, over the same relevant time period, Defendants and their co-conspirators, as described above, engaged in this conspiracy and/or concerted action to defraud by causing the Plaintiff and the Class to purchase these Subject Drugs for off-label uses that were not approved by the FDA and were not scientifically proven to be safe, efficacious, effective or useful for the conditions for which such Subject Drugs were prescribed, administered and otherwise provided, and for which Plaintiff and members of the Class made payments. Defendants did so by explicitly making and disseminating unsubstantiated and false representations about the safety and efficacy of the Subject Drugs. In the absence of Defendants' conspiracy and concerted action, the Class would not have paid for these drugs at all and would have paid much less for other drugs or alternative treatments which would have been more beneficial in treating their conditions.

323. As detailed above and in the documents incorporated by reference relating to the criminal investigation and charges brought against the Pfizer Defendants, those Defendants have agreed to resolve the federal government's charge of violating Title 21, United States Code, §§ 331(a), 333(a)(2) and 352.

324. Pursuant to their conspiracy and/or concerted action alleged herein, Defendants and their co-conspirators engaged in a wide range of activities the purpose and effect of which was to defraud the Plaintiff and the Class. These activities have been set forth in great detail above and throughout this Complaint, and have been incorporated by reference herein, including, but not limited to, the following activities:

(a) Defendants discussed and agreed among themselves and with their co-conspirators to offer, provide and accept kickbacks and bribes in exchange for the improper sales of these Subject Drugs for both indicated and off-label uses, thereby resulting in the Defendants obtaining additional revenues and profits from their fraudulent sales and marketing scheme regarding these Subject Drugs for off-label uses as well as their fraudulent sales and marketing scheme regarding these Subject Drugs for indicated uses; and

(b) Defendants discussed and agreed among themselves and with their co-conspirators to create the above-alleged fraudulent scheme to carry out their common purpose and goal of deriving huge profits from their fraudulent sales and marketing scheme regarding these Subject Drugs for off-label uses as well as their fraudulent sales and marketing scheme regarding these Subject Drugs for indicated uses.

325. As discussed throughout this Complaint, Defendants acted in concert with one another, with physicians and healthcare providers and with other co-conspirators throughout the country, to commit the conduct and scheme described herein to defraud Plaintiff and the Class, and acted pursuant to a common design or plan with respect to the fraudulent scheme and conspiracy. As described in this Complaint, Defendants gave substantial assistance or encouragement to each other, to physicians and healthcare providers, and to other co-

conspirators throughout the country in furtherance and as part of the fraudulent scheme and conspiracy in order to defraud Plaintiff and the Class.

326. Defendants' conspiracy and concerted actions have directly and proximately caused the Plaintiff's and the Class members' damages. As a direct and proximate result of Defendants' conspiracies and/or concerted actions perpetrated upon Plaintiff and the Class, Defendants are jointly and severally liable to Plaintiff and the Class for all damages Plaintiff and the Class have sustained, plus exemplary damages and, punitive damages, as well as the cost of suit and reasonable attorneys' fees.

WHEREFORE, Plaintiff, M.A.C., by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

FOURTH CLAIM FOR RELIEF
Unjust Enrichment

327. Plaintiff, M.A.C., by and through his mother Karen Caltieri, incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

328. Plaintiff brings this claim on behalf of himself and the Class.

329. By engaging in the conduct described in this Complaint, Defendants knowingly obtained benefits from the Plaintiff and the Class under circumstances such that it would be inequitable and unjust for these Defendants to retain them.

330. Defendants have collected payments for these Subject Drugs from Plaintiff and members of the Class that vastly exceeded the payments to which Defendants were entitled as a matter of law. In exchange for these payments, and at the time they made these payments, Plaintiff and members of the Class expected that their physicians were not prescribing these Subject Drugs due to Defendants' kickbacks, bribes or payment or provision of illegal

remuneration or other illegal inducements; that these Subject Drugs were safe, medically efficacious, effective and useful for the particular conditions or symptoms for which they were prescribed; and that these Subject Drugs, in instances where these Subject Drugs were provided for FDA-approved conditions, were also being provided and administered in doses and over durations that were FDA-approved. Plaintiff and the Class would not have purchased the Subject Drugs in the absence of Defendants' wrongful conduct.

331. Thus, Defendants will be unjustly enriched if they are permitted to retain the full amounts paid to them by Plaintiff and the members of the Class.

332. Plaintiff and the members of the Class are therefore entitled to an award of compensatory and punitive damages in an amount to be determined at trial or to the imposition of a constructive trust upon the wrongful profits obtained by, revenues obtained by, and benefits conferred upon Defendants as a result of their wrongdoing and the purchases made by Plaintiff, and members of the Class.

333. Plaintiff and the members of the Class have no remedy at law to prevent Defendants from continuing the inequitable conduct alleged herein and the continued unjust retention of the payments made to Defendants on behalf of Plaintiff and members of the Class.

WHEREFORE, Plaintiff, M.A.C., by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seek the relief set forth below.

FIFTH CLAIM FOR RELIEF
Tortuous Interference With Contractual Relations

334. Plaintiff, M.A.C., by and through his mother Karen Caltieri, incorporates by reference all preceding paragraphs, as well as the paragraphs that follow in this Complaint, as if fully set forth herein.

335. Plaintiff brings this claim on behalf of himself and the Class.

336. The Plaintiff and the Class were patients who had contractual relationships with their treating physicians.

337. As part of those contractual relationships, the physicians provided health care services in exchange for monetary compensation.

338. Defendants were aware that those physicians had contractual relationships with the Plaintiff and the Class, and that those physicians write prescriptions for said patients as part of that contractual relationship.

339. Without justification, through illegal and unethical marketing of the subject drugs, and other previously described conduct and practices, the Defendants intentionally interfered with those contractual relationships, and induced those physicians to prescribe the subject drugs to the Plaintiff and the Class, instead of alternative drugs which were cheaper and more effective.

340. As a result of the Defendants' interference with patients' and physician's contractual relationships, Plaintiff and the Class suffered damages because they paid for subject drugs that were ineffective, paid more for the subject drugs than they would have paid for cheaper and more effective alternatives, and were denied effective treatment for their medical conditions while they were prescribed the subject drugs.

WHEREFORE, Plaintiff, M.A.C., by and through his mother Karen Caltieri, on behalf of himself and the members of the Class, respectfully seeks the relief set forth below.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff, M.A.C., by and through his mother Karen Caltieri, and the Class and all Subclasses, demands judgment against the Defendants in each claim for relief, jointly and severally, and as follows:

(a) On the claim under the consumer protection statutes of Massachusetts and the 49 remaining states, the District of Columbia and Puerto Rico, compensatory damages, treble damages, punitive damages, and any other damages permitted under such statutes, such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees;

(b) On the conspiracy/concert of action claim, compensatory damages, treble damages and punitive damages, such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees;

(c) On the claim for unjust enrichment and tortuous interference with contractual relations, recovery in the amount paid on behalf of Plaintiff and the Class' (i) payments for these Subject Drugs to treat conditions for which these drugs were not approved by the FDA; (ii) over-payments for these Subject Drugs resulting from Defendant-promoted treatment with excessive dosages or over excessive durations that were not FDA-approved, even if the underlying medical conditions for use were FDA-approved; (iii) payments for these Subject Drugs where Plaintiff's and the Class' purchases arose from bribes, kickbacks, illegal remuneration or other illegal inducements paid or provided to their physicians by the Defendants, and (iv) payments for these Subject Drugs to treat conditions for which the Subject Drugs were

not effective and for which Defendants disseminated unsubstantiated and/or false representations about the safety and efficacy of the Subject Drugs that induced providers to prescribe the Subject Drugs for those conditions in such amounts to be determined at trial, plus Plaintiff's costs in this suit and reasonable attorneys' fees;

(d) Awarding Plaintiff and the Class other appropriate equitable relief, including, but not limited to, disgorgement of all profits obtained from their wrongful conduct and declaratory and injunctive relief;

(e) Awarding Plaintiff and the Class pre-judgment and post-judgment interest at the maximum rate allowed by law;

(f) Awarding Plaintiff and the Class their costs and expenses in this litigation, including expert fees, and reasonable attorneys' fees; and

(g) Awarding Plaintiff and the Class such other and further this relief as may be just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: May 10, 2010

Respectfully submitted,

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